IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

United HealthCare Services, Inc.,

Plaintiff,

v.

Celgene Corporation,

Defendant.

Civil No. _____

COMPLAINT

JURY TRIAL DEMANDED

TABLE OF CONTENTS

Plaintiff United HealthCare Services, Inc. ("Plaintiff" or "UHS"), by and through its undersigned attorneys, complains and alleges against Defendant Celgene Corporation ("Celgene" or "Defendant") as follows:

I. NATURE OF THE CASE

1. This civil antitrust action arises from Defendant Celgene's successful efforts to exclude generic competitors from selling AB-rated equivalents to Thalomid® (thalidomide) and Revlimid® (lenalidomide). As set forth more fully below, Celgene's course of conduct has successfully limited competition, deprived purchasers of choice, and dramatically increased the prices that purchasers have paid – and will continue to pay – for these drugs.

2. Thalidomide was sold in the 1950s and 1960s as a sedative and anti-nausea medication but was shown to be cause serious birth defects and sales of the drug were banned. After the ban was lifted in 1998, Celgene obtained U.S. Food and Drug Administration ("FDA") approval to market Thalomid for a leprosy complication known as erythema nodosum leprosum ("ENL"). Before granting approval, the FDA required restricted distribution programs to protect against fetal exposure to Thalomid.

3. In 2005, Celgene successfully developed Revlimid, a thalidomide analog, and obtained FDA approval to market it for a specific chromosomal variant of myelodysplastic syndromes ("MDS"). Celgene would go on to obtain FDA approvals for additional Revlimid indications, including for a subset of multiple myeloma ("MM")

patients in 2006,[1] and later for a subset of mantle cell lymphoma ("MCL") patients in 2013. The FDA required restricted distribution programs for Revlimid as well. Thalomid was also indicated for MM.

4. But Celgene did more than simply focus on the science of thalidomide after Thalomid's FDA clearance. Greed overtook science and Celgene engaged in a course of conduct that prevented free and fair competition so that Celgene could charge unlawfully high prices for Thalomid and Revlimid.

5. Celgene constructed an impenetrable monopolistic fortress and engaged in a multipronged scheme to unlawfully maintain 100% share of the market for these two drugs, and massively inflate its profits, by successfully interfering with competitors' efforts to develop and/or obtain FDA approval for generic versions of Revlimid and/or Thalomid in many ways:

- Celgene unlawfully used its restricted distribution programs to prevent would-be competitors (only) from obtaining samples of the active pharmaceutical ingredients ("API") that were required to develop AB-rated generics;

[1] Under the FDA's orphan drug exclusivity program, 21 U.S.C. §§ 360aa-cc, the FDA may not approve a generic equivalent for a specific indication or "rare disease" that a brand drug is FDA- approved to treat for a period of seven (7) years. MM is such a "rare disease." Therefore, until May 25, 2013, the FDA could not approve a generic thalidomide for the treatment of MM. It could, nevertheless, approve generic thalidomide for the treatment of other indications. This is known as a "skinny label."

- Celgene prevented pharmacies and ingredient suppliers from acting as alternative sources of samples for such would-be generic competitors;
- Celgene fraudulently obtained various patents from the U.S. Patent and Trademark Office ("USPTO") for Thalomid and Revlimid and their associated safety distribution protocols;
- Celgene commenced serial sham patent infringement lawsuits; and
- Celgene filed baseless citizen petitions with the FDA to stymie generic approvals.

6. In the rare instances where Celgene's efforts failed to prevent a would-be competitor from prosecuting an Abbreviated New Drug Application ("ANDA"), and FDA approval of an ANDA for a generic version of Revlimid or Thalomid became possible, Celgene entered into confidential settlements with its competitors that may have included anti-competitive reverse payments. The federal government routinely has criticized—and challenged in court—the same sort of anticompetitive practices in which Celgene engages.[2]

[2] *See, e.g.,* Federal Trade Commission, *Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions* (Jan. 2010), https://www.ftc.gov/sites/default/files/documents/reports/pay- delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

7. Since 2006, Celgene has recorded more than $35 billion of Revlimid sales and $3 billion of Thalomid sales. In 2006, a month's supply of Revlimid cost $6,195.[3] In 2010, the price was about $8,000 for a one-month supply. Now, a twenty-eight (28) day supply of Revlimid costs patients and their health insurance payors as much as $20,000, and a twenty-eight (28) day supply of Thalomid costs them as much as $10,000. In 2016, Celgene's total revenue was $11.229 billion, of which $6.974 billion was from Revlimid and $152.1 million was from Thalomid. When Thalomid first entered the market, it cost approximately $6 per capsule. In 2014, its price soared to as much as $357 per capsule.

8. For many years leading up to 2016, Celgene routinely increased its price either once or twice per year. Celgene avoided driving down demand since its illegal conduct prevented generic alternatives from competing. With the benefit of its unlawful monopoly, Celgene engaged in other tactics to improperly drive prescription volume and market price. For example, Celgene paid certain physicians to write prescriptions and secretly funneled money through charities to underwrite copayments for potential patients.

9. Celgene's illicit efforts with respect to Thalomid and Revlimid have been enormously profitable. Witness these drugs' net product sales:[4]

[3] Katherine Streeter, *How A Drugmaker Gamed The System to Keep Generic Competition Away* (May 17, 2018), https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a- drugmaker-gamed-the-system-to-keep-generic-competition-away.

[4] Net product sales figures drawn from Celgene's Annual Reports/Form 10-K filings.

	2018	2017	2016	2015	2014	2013	2012	2011	2010	2009
Revlimid	$9.7B	$8.2B	$7.0B	$5.8B	$5.0B	$4.3B	$3.8B	$3.2B	$2.5B	$1.7B
Thalomid	$114M	$132M	$152M	$185M	$221M	$245M	$302M	$339M	$387M	$437M

10. Fast forward to 2018: Celgene's worldwide sales were projected to exceed $14.4 billion and Revlimid net sales are projected around $9.4 billion.[5] As of 2017, it was the second-highest grossing drug on Earth.[6] Revlimid is projected to reach nearly $14 billion in worldwide sales by 2022.[7]

11. There has never been a generic substitute for Revlimid or Thalomid available in the U.S., enabling Celgene to price the drugs at levels unrestrained by generic competition.

12. Celgene's anticompetitive tactics to block generic entry have caused UHS to pay supracompetitive prices for these drugs in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, in addition to state antitrust and consumer protection laws. UHS seeks civil damages for the overcharges it paid as a result of Celgene's conduct.

[5] Zacks Equity Research, *Celgene Provides 2017 Preliminary Results and 2018 View* (Jan. 9, 2018), https://www.nasdaq.com/article/celgene-provides-2017-preliminary-results-2018-view- cm902808.

[6] Amy Brown, *EP Vantage 2017 Preview* (Dec. 2016), http://info.evaluategroup.com/rs/607- YGS-364/images/EPV2017Prev.pdf.

[7] Evaluate Ltd., *EvaluatePharma Orphan Drug Report 2017* (Feb. 2017), http://info.evaluategroup.com/rs/607-YGS-364/images/EPOD17.pdf. Not surprisingly, Revlimid was the top-selling "orphan drug" in the United States in 2016. *Id.* "An orphan drug is a pharmaceutical product aimed at rare diseases or disorders." *Id.*

II. JURISDICTION AND VENUE

13. This Court has jurisdiction over this action pursuant to 15 U.S.C. § 26, and 28 U.S.C. §§ 1331, 1332, and 1337. Plaintiff asserts federal claims for injunctive relief under Section 2 of the Sherman Act, 15 U.S.C. § 2, and Section 16 of the Clayton Act, 15 U.S.C. § 26.

14. This Court has jurisdiction over the state law claims alleged in this action pursuant to 28 U.S.C. § 1367, as the state law claims are so related as to form part of the same case or controversy. Such supplemental or pendant jurisdiction will also avoid unnecessary duplication and multiplicity of actions, and should be exercised in the interests of judicial economy, convenience, and fairness. The court would also separately have jurisdiction over these claims under 28 U.S.C. § 1332(a), as the amount in controversy exceeds $75,000.00 and involves diversity of citizenship.

15. Venue is proper in this District pursuant to 15 U.S.C. § 22, and 28 U.S.C. § 1391. At all relevant times, Defendant resided, transacted business, and/or was found or had agents in the United States, including this District. Defendant is and has at all relevant times been registered to do business in the State of Minnesota, maintains a designated agent for service of process in Minnesota, and employs sales and other personnel in this District for the purpose of marketing, selling, and distributing pharmaceuticals, including the subject drugs, in Minnesota. During the alleged time period, Defendant marketed, sold and/or shipped the pharmaceutical drugs at issue in a continuous and uninterrupted flow of interstate commerce in the United States, including into this District. Defendant's conduct alleged herein had a direct,

substantial, and reasonably foreseeable effect on interstate commerce in the United States, including in this District. Defendant's conduct in artificially increasing prices for the drug products at issue was directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the United States, including in this District specifically, and Defendant is otherwise subject to the service of process provisions of 15 U.S.C. § 22.

16. Defendant is subject to the personal jurisdiction of this Court for one or more of the reasons stated below:

a. Defendant is subject to service of process for this action as provided in 15 U.S.C. § 22

b. Defendant is amenable to service of process because, as alleged in this Complaint, it inhabits, transacts business in, has continuous or systematic contacts with, and/or is found or has sufficient minimum contacts in the United States sufficient to satisfy due process. While Defendant is headquartered outside this District, it nevertheless engaged in the business of developing, distributing, advertising and/or selling the drug products at issue into this District specifically and purposefully.

c. Defendant is amenable to service of process pursuant to Rule 4(k)(1)(A) of the Federal Rules of Civil Procedure and the long-arm statute of the State in which this Federal Court sits because, *inter alia*, and as alleged in this Complaint, Defendant has transacted business in this District and has contracted to supply services or things in this District, and because the

District's long-arm statute extends jurisdiction to the limits of due process and Defendant has sufficient minimum contacts with the District to satisfy due process; and/or

d. Based on the allegations in this Complaint, Defendant is subject to the general and specific personal jurisdiction of this Court because it has purposefully directed its contacts and conduct at the forum District and has purposefully availed itself of the laws of this District. As alleged in this Complaint, Defendant engaged in anticompetitive conduct that was intended to have, and did have, direct, substantial and reasonably foreseeable effects on the commerce throughout the United States, including this District; and

e. Defendant is and has at all relevant times been registered to do business in the State of Minnesota, and maintains a designated agent for service of process within the State of Minnesota.

III. PARTIES

17. Plaintiff UHS is a corporation organized and existing under the laws of Minnesota with its principal place of business in Hennepin County, Minnesota. It is a wholly owned subsidiary of UnitedHealth Group, Inc. ("UHG"), which is also headquartered in Minnetonka, Minnesota.

18. UHS engages in servicing prescription drug managed care programs provided to members and beneficiaries under insurance plans offered by UHS's subsidiaries and affiliates, which, together, constitute the largest single health insurance

carrier and services provider in the United States, and serve some 70 million individual insureds ("UnitedHealthcare Insureds").[8] UHS is the centralized and primary contracting entity responsible for payments made for pharmaceutical drugs dispensed to UnitedHealthcare Insureds throughout the country. From its headquarters in Hennepin County, Minnesota, UHS negotiated and executed contracts with Pharmacy Benefit Managers ("PBMs") on behalf of itself and its health plan subsidiaries and affiliates ("UnitedHealthcare Plans"), and during the relevant time period, was (and is) contractually responsible for the payments made under those contracts, including for thalidomide and lenalidomide drug products dispensed to UnitedHealthcare Insureds during the relevant time period.

19. UHS is the parent company of, or otherwise an affiliate/related company to, each of the UnitedHealthcare Plans, which issue health insurance to UnitedHealthcare Insureds, including for coverage of prescription drug costs. The UnitedHealthcare Plans issue insurance to UnitedHealthcare Insureds covering prescription drugs in the form of (1) fully insured commercial ("Commercial") plans; (2) Medicare plans; and (3) Medicaid plans. The UnitedHealthcare Plans provide these prescription drug insurance benefits to UnitedHealthcare Insureds in all 50 states, the District of Columbia, and Puerto Rico. These UnitedHealthcare Plans are listed in the attached Exhibit A.

[8] For purposes of this Complaint, the term UnitedHealthcare Insureds does not include members of self-insured or self-funded health plans, also known as self-funded or Administrative Services Only ("ASO") customers.

20. UHS is also an affiliate and the assignee of OptumRx Group Holdings, Inc., OptumRx, Inc., and their wholly owned pharmacy subsidiaries as pertaining strictly to the purchases made for or arising out of the business of their wholly owned pharmacy subsidiaries (collectively, "Pharmacy Assignors"). Pharmacy Assignors buy prescription drugs and dispense them to prescribed consumers, on a specialty and/or mail order retail pharmacy basis. Pharmacy Assignors have purchased substantial quantities of the pharmaceutical drugs at issue (thalidomide and lenalidomide products) directly from Celgene, and have assigned to UHS their claims and the rights to obtain all recoveries arising out of such direct purchases and the matters alleged in this Complaint.

21. UHS seeks recovery for all unlawful overcharges it incurred in connection with indirectly paying for thalidomide and lenalidomide products dispensed to UnitedHealthcare Insureds, including all those receiving insurance or health benefits from any of the UnitedHealthcare Plans (or their predecessors or successors). UHS also seeks recovery for all unlawful overcharges incurred in connection with direct purchases of thalidomide and lenalidomide drug products from Celgene by Pharmacy Assignors.

22. UHS is the proper entity to pursue all forms of relief, including damages, for all injury and losses incurred as alleged in this Complaint. Nonetheless, out of an abundance of caution, and to assure the Court that there is no potential for any duplicative indirect purchaser/payor recovery, UHS has obtained assignments from the UnitedHealthcare Plans, conveying to UHS any claims and rights to recoveries they

may have in connection with the matters alleged in this Complaint. UHS hereby asserts those assigned indirect purchaser/payor claims in the alternative to the claims of UHS, to the extent that such assignors are found to be sole owners of any claims that are non-duplicative to those of UHS. Accordingly, to the extent that the Court were to find such assignments are required for any claims, all subsequent references to "UHS" include itself and assignors UnitedHealthcare Plans, unless expressly indicated otherwise.

23. UHS timely excluded itself from the certified settlement class of end-payor plaintiffs in No. 14-cv-6997 (D.N.J.) (the "putative end-payor class action"). Pursuant to the United States Supreme Court decision in *American Pipe Construction Co. v. Utah*, 414 U.S. 538 (1974), and its progeny, statute of limitations periods applicable to UHS's claims were tolled from the filing of the initial putative end-payor class action to the date of UHS's exclusion from the certified settlement class.[9] In addition, Celgene's unlawful conduct was unbeknownst to UHS prior to April 2014, when Mylan initiated its lawsuit against Celgene and laid out detailed allegations about anticompetitive conduct that Celgene had engaged in. UHS has suffered injuries from the unlawful conduct alleged in this complaint through the present based upon its payments for Revlimid and Thalomid priced at supracompetitive levels.

24. Defendant Celgene Corporation is a drug manufacturer, incorporated in Delaware and headquartered at 86 Morris Avenue, Summit, New Jersey. It is publicly-

[9] The initial putative class action complaint was filed on November 7, 2014.

traded under the NASDAQ symbol "CELG." Celgene manufactures and markets the thalidomide and lenalidomide drug products Thalomid and Revlimid.

IV. ECONOMIC BACKGROUND

25. Drug manufacturers like Celgene have exploited U.S. laws regulating the prescription and dispensing of medicine to establish illegal, anticompetitive drug monopolies.

26. For most consumer products, the person responsible for paying for them is also the person selecting them. The pharmaceutical marketplace departs from this norm.

27. Prescription drugs may only be dispensed pursuant to a doctor's prescription, and a licensed pharmacist may dispense only the brand-name drug named in the prescription or its AB-rated, FDA-approved generic equivalent.[10]

28. In most instances, a health insurance payor pays for the prescription drug that a doctor has prescribed to the patient, often with a patient co-pay. Like for the pharmacist, the "choice" is limited to the drug named in the prescription or its AB-rated generic equivalent. Therefore, the doctor's prescription defines the relevant product market, because it limits the dispensable drug options to the drug named therein.

29. When there is not generic competition for a brand-name drug, the brand manufacturers can set and maintain prices without losing market share. The ability to

[10] In many states, pharmacists must substitute an AB-rated generic for a brand-name drug without seeking permission from the prescribing doctor.

do this is the result of the brand-name drug company's monopoly power over the market for that drug in both its brand-name and generic form. When an AB-rated generic is available, price is reintroduced to the product selection decision at the pharmacy counter, and the disconnect between choice and payment is lessened, disabling the brand manufacturer from exploiting that disconnect. Generic introduction restores normal competitive pressures.

30. Typically, AB-rated generic versions of brand-name drugs are priced significantly below their brand-name counterparts. When multiple generic manufacturers enter the market, prices for generic versions of a brand-name drug predictably decrease, sometimes as much as by 90%, because of price competition among generic manufacturers.[11] The FDA reports that, in 2010, the use of FDA-approved generics saved $158 billion, or $3 billion per week, and that one (1) year after entry, a generic drug takes over 90% of the corresponding brand-name drug's sales at 15% of the price. Generic drug entry, therefore, is a huge threat to the continued profitability of a branded drug.

31. As the price gap between the brand-name drug and its corresponding generic drug widens, the former's sales volume shrinks. Price is the only material difference between a brand-name drug and its AB-rated generic equivalent.

[11] *See, e.g.*, Jon Leibowitz, "Pay for Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (June 23, 2009), http://www.ftc.gov/sites/default/files/documents/public_statements/pay-delay-settlements- pharmaceutical-industry-how-congress-can-stop-anticompetitive-conduct-protect/090623payfordelayspeech.pdf.

32. Generic competition enables direct purchasers (like Pharmacy Assignors) and end-payors (like UHS) to pay for a generic version of a brand-name drug at substantially lower prices. However, until generic manufacturers enter the market with an AB-rated generic, there is no generic drug which competes effectively with the brand-name drug, and therefore, the brand-name manufacturer can continue to charge supracompetitive prices without losing sales. Given their acute knowledge of the effects of generic entry into a market, brand-name manufacturers like Celgene have a strong incentive to delay the entry of a generic drug onto the market, including by entering illegal reverse "pay for delay" settlement agreements and serially filing frivolous patent infringement lawsuits, among other anticompetitive tactics.

V. THE REGULATORY BACKGROUND

A. The Hatch-Waxman Act and NDA Approval Process

33. Under the Federal Food, Drug and Cosmetics Act (21 U.S.C. §§ 301-392) ("FDCA"), a manufacturer that creates a new, pioneer drug must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and efficacy of the drug and identify any patents claiming the drug. 21 U.S.C. § 355(b).

34. When the FDA approves a brand-name manufacturer's NDA, it lists in a publication entitled the "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the "Orange Book") any patents which, according to the information supplied to the FDA by the brand-name manufacturer: (1) claim the approved drug or its approved uses; and (2) for which a "claim of patent infringement

could reasonably be asserted if a person is not licensed by the owner engaged in the manufacture, use, or sale of the drug."[12]

35. The FDA does not investigate the patents or verify the NDA sponsor's representations for accuracy or trustworthiness prior to listing patents in the Orange Book. It is a pure administrative and clerical act.

36. Once a brand manufacturer lists a patent in the Orange Book, it puts potential generic competitors on notice that the brand considers the patent to cover its drug.

B. The Hatch-Waxman Act and ANDA Approval Process

37. In 1984, Congress amended the FDCA with the enactment of the Hatch-Waxman Act ("Hatch-Waxman"). Congress' principal intent was for Hatch-Waxman to simplify and reduce the regulatory hurdles for prospective generic manufacturers, by replacing the lengthy and costly NDA approval process with an expedited ANDA review process.[13] Under Hatch- Waxman, an ANDA applicant may rely on the safety and efficacy findings of the NDA for the referenced brand-name drug, if the ANDA demonstrates the proposed generic drug is therapeutically equivalent and "bioequivalent," ("BE") *i.e.*, it contains the same active ingredient(s), dosage form, route of administration, and strength as the brand-name drug, and is absorbed at the

[12] 21 U.S.C. § 355(b)(1); 21 U.S.C. § 355(g)(7)(A)(iii).

[13] Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman").

same rate, and to the same extent, as the brand-name drug. For ANDAs that pass this test, the FDA assigns an "AB" rating to the generic drug.

38. BE is generally demonstrated via studies in which the proposed generic is compared to the Reference Listed Drug ("RLD," which is, in this instance, the brand-name drug) in either *in vivo* or *in vitro* studies.[14] These studies require the ANDA applicant to have access to sufficient samples of the RLD to conduct the necessary comparisons. Without RLD samples, it is impossible to complete and file an ANDA application.

39. The FDA illuminates the issue:

> To obtain approval for a generic drug, the generic company needs to show, among other things, that its version of the product is bioequivalent to the RLD [i.e. the brand drug, or reference listed drug]. This usually requires the generic company to conduct bioequivalence studies comparing its product to the RLD, and to retain samples of the RLD used in testing after a study is complete. To conduct these kinds of bioequivalence studies, the generic company needs to obtain samples (generally between 1,500 and 5,000 units) of the RLD.[15]

40. Only samples of the RLD approved by the FDA and marketed in the United States may be used for BE testing purposes. In the ordinary course, a prospective ANDA sponsor obtains samples by buying them, at market price, from a

[14] *In vivo* studies are studies conducted on live subjects. *In vitro* studies are conducted in a laboratory.

[15] FDA, *Reference Listed Drug (RLD) Access Inquiries*, https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm (last visited Feb. 26, 2019).

drug wholesaler or distributor. Wholesalers and distributors are large companies that buy drugs from manufacturers for the purpose of re-selling them to pharmacies or other entities. Generic companies are authorized to buy prescription drugs from distributors for BE testing purposes.

41. Celgene's own former senior vice president of global regulatory affairs, drug safety, risk management, and quality assurance Graham Burton has admitted that Celgene is the only source from which a generic company could obtain Thalomid or Revlimid for purposes of BE testing.[16]

C. The Hatch-Waxman's Balancing Act

42. As a counterbalance to Hatch-Waxman's simplified ANDA process, Hatch-Waxman also provides brand manufacturers with the ability, merely by filing a patent infringement lawsuit, to easily obtain what is essentially a preliminary injunction, in the form of an automatic stay of up to thirty (30) months, of the FDA's ability to approve a generic manufacturer's ANDA.

43. To obtain FDA approval of an ANDA, the generic manufacturer must certify that it will infringe no patent listed in the Orange Book claiming the brand drug, because either:

a. No patent for the brand-name drug has been filed with the FDA (a "Paragraph I Certification");

[16] Exhibit to Brief in Opposition to Motion for Summary Judgment, *Mylan Pharmaceuticals, Inc. v. Celgene Corp.*, No. 2:14-cv-02095-ES-MAH (D.N.J. Mar. 20, 2018) ("MSJ Opp."), Dkt. No. 285-15 at 69-70.

b. The patent for the brand-name drug has expired (a "Paragraph II Certification");

c. The patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III Certification"); or

d. The patent for the brand-name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV Certification").[17]

44. When a generic manufacturer files a Paragraph IV Certification, it must notify the brand manufacturer and patent owner. The ANDA filing itself becomes an artificial act of patent infringement, entitling the patent holder to sue for injunctive relief, according to Hatch-Waxman.

45. If the patent holder sues the ANDA filer within forty-five (45) days of receiving the Paragraph IV Certification, Hatch-Waxman prevents the FDA from granting final approval to the ANDA until the earlier of (a) thirty (30) months after the lawsuit is commenced, or (b) the court presiding over the patent infringement action rules that the patent is invalid or not infringed by the ANDA.[18] It is almost always the case that the thirty (30) months expire before the court rules, resulting in a 30-month statutory stay.

[17] 21 U.S.C. § 355(g)(2)(A)(vii).

[18] 21 U.S.C. § 355(j)(5)(B)(iii).

46. However, during the 30-month stay, the FDA may grant "tentative approval" to an ANDA applicant if the agency determines that the ANDA would qualify for final approval, but for the 30-month stay.

47. Hatch-Waxman grants a 180-day period of market exclusivity to the first Paragraph IV ANDA applicant ("first filer") to file a substantially complete ANDA. During the 180-day exclusivity period (measured from the first commercial marketing of the generic drug or the date of a court decision finding the listed patent invalid, unenforceable, or not infringed[19]), the first ANDA filer enjoys 180 days of freedom from competition from other generic versions of the drug, and during that period can capture almost all of the market for the drug while selling the generic for a higher price than the market will support once additional generics enter the market.

48. Congress enacted the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA").[20] The MMA creates numerous conditions under which a first filer forfeits its 180-day exclusivity, thereby allowing other ANDA filers to enter the market. For example, forfeiture occurs if the first filer fails to obtain tentative approval within thirty (30) months from filing, unless the failure is caused by a change in, or review of, the approval requirements.

49. Under the "Agreement with another applicant" provision, the first filer will forfeit its exclusivity if it "enters into an agreement with another applicant under

[19] 21 U.S.C. § 355(j)(5)(B)(iv)); *see also* 21 C.F.R. § 314.107(c)(1)).

[20] Public Law 108-173; 21 U.S.C. A. § 355(j)(5)(D).

this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the [Paragraph IV certification] ...."[21]

50. Under the "failure to market" provision, a first filer forfeits its 180-day exclusivity if it fails to market its generic drug by the *later of*:

> (a) *the earlier* of the date that is:
>
> > (1) 75 days after receiving final FDA approval; or
> >
> > (2) 30 months after the date it submitted its ANDA; or
>
> (b) the date that is 75 days after the date as of which, as to each of the patents qualifying the first applicant for exclusivity (i.e., as to each patent for which the first applicant submitted a Paragraph IV certification), at least one of the following has occurred:
>
> > (1) a final decision of invalidity or non-infringement;
> >
> > (2) a settlement order entering final judgment including a finding the patent is invalid or not infringed; or
> >
> > (3) the NDA holder delists the patent from the Orange Book.[22]

51. Branded-manufacturers and first filers, if they enter into an agreement, can structure such an agreement to circumvent the above provisions and keep the 180-day exclusivity in place by, among other things, settling their litigation before a final judgment of invalidity or non-infringement can be entered, or by seeking a consent

[21] 21 U.S.C. A. § 355(j)(5)(D)(i)(V).

[22] 21 U.S.C.A. § 355(j)(5)(D)(i)(I).

judgment that does not include a finding that all the patents for which the first filer submitted a Paragraph IV Certification were invalid or not infringed. Consequently, a subsequent ANDA filer can fight this only by itself obtaining a judgment that all patents for which the first filer filed a Paragraph IV Certification are invalid or not infringed, thereby triggering forfeiture of the first filer's 180-day exclusivity rights.

D. Risk Evaluation and Mitigation Strategies Programs

52. Since at least the 1960s, the FDA has examined and implemented various methods for managing risks related to pharmaceutical products. Methods have included disclosure and labelling requirements. The Controlled Substance Act of 1970 saw the regulation of manufacturers, prescribers, dispensers, and labels and permitted the FDA to require warnings on packages.[23]

53. In the 1990s, the FDA began to work with manufacturers to develop risk management programs for drugs with dangerous side effects. Then, in the 2000s, the FDA established Risk Minimization Action Plans ("RiskMAPs"), in which manufacturers voluntarily instituted risk minimizing plans.

54. In 2007, Congress passed the Food and Drug Administration Amendments Act ("FDAAA"), which codified the Risk Evaluation and Mitigation Strategies ("REMS") to be implemented with respect to certain pharmaceutical products "that

[23] 21 U.S.C. § 801 *et seq.* (2002).

have already been approved" and directs the Secretary of Health and Human Services ("HHS") to establish an active post- market drug surveillance infrastructure.[24]

55. A REMS can include, *inter alia*, a medication guide, patient package inserts, and/or restrictions on the distribution of the drug.

56. Since their enactment in 2007, REMS have been increasingly common in the FDA approval process; roughly 40% of new drugs have REMS programs.

57. REMS are intended to give the FDA authority to condition drug approval on the implementation of a program designed to address serious risks associated with particular pharmaceutical products. The intention is not to make drugs, or drug samples, less available. In fact, §505-1(f)(8) explicitly prohibits brand manufacturers from using REMS to "block or delay approval of" an ANDA. The FDAAA does not prohibit the sale of REMS-subject drugs to generic manufacturers that will use those drugs in controlled BE testing, nor does it give an NDA holder the right to interfere with a competitors' ability to purchase necessary drug samples.

E. Celgene and Other Brand-Name Drug Manufacturers Abused REMS to Block Generic Competition

58. Celgene and other brand manufacturers know that competition from generics devastates their profits as prices erode and the brand loses market share. Brand manufacturers are highly motivated to delay or block generic entry by extending their monopoly beyond its legal limits. Brand manufacturers have come to do this through, *inter alia*, abusing and "gaming" REMS programs.

[24] 21 U.S.C. § 355-1(f)(8).

59. Janet Woodcock, Director of the FDA's Center for Drug Evaluation and Research ("CDER") testified in 2016 that brand companies use REMS programs "as an excuse to not give the drug to the generics so they can compare it to their drug." This behavior, she noted, causes "barriers and delays in getting generics on the market."[25]

F. State and Federal Government Regulators Have Targeted REMS Abuse

60. REMS abuse has come under increasing fire as generics' resulting inability to enter the market has increased U.S. healthcare costs by more than $5 billion annually.[26]

61. In July 2010, the FDA commented that REMS programs should not be used for anticompetitive reasons.[27]

62. In January 2013, the Connecticut Attorney General's office wrote to Celgene that Celgene's responses to government inquiry "has raised serious concerns in my office that, notwithstanding its claims to the contrary, Celgene is not truly willing to sell Revlimid samples in a manner that would allow the BE testing necessary for a competitor to submit an ANDA….Celgene's current actions raise the specter that the

[25] Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs: Hearing Before the S. Comm. on Health, Educ., Labor & Pensions, 114th Cong. 31 (2016) (testimony of Janet Woodcock, Director, Center for Drug Evaluation & Research).

[26] Association for Accessible Medicines, *Increase Competition & Access – Support CREATES Act*, https://accessiblemeds.org/campaign/increase-competition-and-access-rems (last visited Feb. 26, 2019).

[27] *See* Center for Drug Evaluation and Research, FDA, Risk Evaluation and Mitigation Strategy (REMS) Public Meeting (July 28, 2010), at 270-71 (statement by Jane Axelrad, Associate Director of Policy, Center for Drug Evaluation and Research).

discussions have been nothing but an artifice to continue to allow Celgene to delay the development of a generic alternative to Revlimid."[28]

63. Some estimates on the cost of REMS abuse are as high as $5.2 billion on the federal government, and $5.8 billion on private market participants like UHS and its assignors.[29]

64. In an effort to combat rampant REMS abuse and to facilitate access to samples of REMS-subjected drugs, the FDA began issuing "safety determination" letters to brand companies that confirmed that the FDA would not consider providing samples of the RLD for generic BE testing to be a violation of REMS. In 2014 the FDA stated:

> In the interest of facilitating prospective generic applicants' access to RLD supplies to conduct the testing necessary to support ANDA approval, FDA has, on request, reviewed the [generic's] BE study protocols proposed by prospective ANDA applicants to assess whether they provide safety protections comparable to those in the applicable REMS ETASU. When the Agency has determined that comparable protections existed, FDA has issued letters to the RLD sponsors stating so and indicating that FDA would not consider it to be a violation of the REMS for the RLD sponsor to provide drug product to the prospective ANDA applicant.[30]

---

[28] Exhibit to MSJ Opp., Dkt. No. 285-21.

[29] Alex Brill, *Unrealized Savings from the Misuse of REMS and Non-REMS Barriers* (Sept. 2018), https://accessiblemeds.org/sites/default/files/2018-09/REMS_WhitePaper_September2018%5B2%5D.pdf.

[30] FDA Center for Drug Evaluation and Research, Draft Guidance: How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD (Dec. 2014), https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm 425662.pdf ("2014 Draft Guidance").

65. Despite the FDA's efforts to help generic manufacturers by issuing such letters, the FDA continues to reiterate that there is no requirement that a generic company seek or obtain such a letter from the FDA: "Requesting or obtaining such a letter from FDA is not a legal requirement."[31]

66. In 2016, a Senate committee concluded that the FDA has "attempted to stymie [brand manufacturers'] obstruction" by providing letters to generic companies indicating that the agency "see[s] no safety risk," but its "actions have been largely ineffective."[32]

67. In 2017, the FDA committed to responding to generic manufacturers' inquiries seeking help accessing samples within sixty (60) days of receipt to mitigate and shorten the delay brand-manufacturers' scheme imposes.

68. On July 27, 2017, the Federal Trade Commission ("FTC") in a Prepared Statement delivered to the United States House of Representatives Subcommittee on Regulatory Reform, Commercial and Antitrust Law warned that "[d]espite clear guidance from both Congress and the FDA that drug firms should not use REMS programs to block or delay generic or biosimilar competition, complaints about abuse of the regulatory process persist…One study estimates that Americans have lost $5.4 billion in annual savings due to delays in accessing drug samples caused by REMS

[31] 2014 Draft Guidance.

[32] Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System, Senate Special Comm. on Aging, 114th Cong. 115 (December 2016), https://www.aging.senate.gov/imo/media/doc/Drug%20Pricing%20Report.pdf.

misuse and other non-FDA mandated restricted distribution programs."[33] In that statement, the FTC explicitly referenced Celgene's actions with respect to Thalomid and Revlimid.

69. On May 17, 2018, the FDA announced that it would begin to regularly publish a list of brand-name drugs that have been the target of complaints that their NDA-holder (or manufacturer) is denying access to samples of RLDs when generic companies seek to buy them. The initial list confirmed that the FDA sent at least twenty-one (21) safety determination letters to at least six (6) brand companies. Its larger list documented fifty-seven (57) different drugs with annual combined sales of $13.0 billion, to which sample access had been denied.

70. Celgene is listed thrice on the list, as the FDA received numerous access inquiries for Celgene's Thalomid, Revlimid, and a third drug not subject to this Complaint, Pomalyst (pomalidomide).[34] The list documents that the FDA received ten (10) inquiries related to Thalomid, thirteen (13) inquiries related to Revlimid, and eight (8) inquiries related to Pomalyst. The FDA issued at least four (4) safety letters for

---

[33] *Antitrust Concerns and the FDA Approval Process*, Prepared Statement Markus H. Heier, Bureau of Competition, Federal Trade Commission before the Subcommittee on Regulatory Reform, Commercial and Antitrust Law, Judiciary Committee, United States House of Representatives, Washington, D.C. (July 27, 2017), https://www.ftc.gov/public-statements/2017/07/prepared-statement-federal-trade-commission-antitrust-concerns-fda.

[34] FDA, *Reference Listed Drug (RLD) Access Inquiries*, https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApprove d/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm (last visited Feb. 26, 2019).

Revlimid, including on July 21, 2012, May 19, 2014, February 22, 2017, and August 15, 2017. The FDA issued safety letters for Thalomid on December 12, 2007, and January 17, 2008.

71. FDA Commissioner Scott Gottlieb stated:

> Today, we're making public a list of companies that have potentially been blocking access to the samples of their branded products. We hope that this increased transparency will help reduce unnecessary hurdles to generic drug development and approval. We often hear of these tactics when it comes to generic drug developer access to samples when the brand products are subject to limited distribution programs. In some cases, these limitations on distribution may be asserted relating to a Risk Evaluation and Mitigation Strategy ("REMS"), a program that the FDA implements for certain drugs to help ensure that the benefits of these drugs outweigh their risks.[35]

72. Gottlieb, in an earlier speech noting the pervasiveness of REMS abuse commented "My message is this: end the shenanigans." He continued:

> [B]randed companies' use of REMS — which FDA adopts as a way to ensure the safe use of certain drugs — is also sometimes being used as a way to frustrate the ability of generic firms to purchase the doses of branded drug that they need to run their studies. This needs to stop… I consider these tactics unfair and exploitative practices, and they're in direct conflict with our broader public health goals.[36]

[35] Statement from FDA Commissioner Scott Gottlieb, M.D., on new agency efforts to shine light on situations where drug makers may be pursuing gaming tactics to delay generic competition (May 17, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm607930.htm.

[36] Scott Gottlieb, M.D., Commissioner of Food and Drugs, Remarks at the Federal Trade Commission: Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics (Nov. 8, 2017), https://www.fda.gov/NewsEvents/Speeches/ucm584195.htm.

73. Then, in a statement it gave to the Department of Health and Human Services in July 2018, the FTC urged action that "carefully considered regulatory and legislative efforts to address REMS abuse."[37] FTC went on that "[b]y improperly blocking the product developer from obtaining samples, the branded manufacturer can potentially delay or indefinitely block generic or biosimilar competition to its product, thereby reducing the competition that Congress specifically sought to facilitate via the Hatch-Waxman Act…."[38]

74. On October 3, 2018, the FTC delivered a prepared statement before the Senate Subcommittee on Antitrust, Competition Policy and Consumer Rights, noting that brands continue to "misuse REMS restrictions to prevent or delay generic firms from obtaining FDA approval for lower cost drugs…."[39]

G. Citizen Petitions

75. Section 505(j) of the FDCA creates a mechanism that allows a person to file a petition with the FDA requesting that the agency take, or refrain from taking, any form of administrative action. This is known as a "citizen petition."

---

[37] *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, Statement of the Federal Trade Commission to the U.S. Department of Health and Human Services (July 16, 2018), *available at* www.ftc.gov/system/files/documents/advocacy_documents/statement-federal-trade-commission-department-health-humanservices-regarding-hhs-blueprint-lower/v180008_commission_comment_to_hhs_re_blueprint_for_lower_drug_prices_and_costs. pdf.

[38] *Id*.

[39] *Oversight of the Enforcement of the Antitrust Laws,* Prepared Statement of the Federal Trade Commission before the Subcommittee on Antitrust, Competition Policy and Consumers Rights, Judiciary Committee, U.S. Senate (Oct. 3, 2018).

76. A citizen petition allows a citizen to notify the FDA of its genuine concerns about safety, scientific, or legal issues regarding a product at any time before or after it enters the market.

77. Pursuant to FDA regulations, the FDA Commissioner must respond to a citizen petition within 180 days of receipt with a grant in whole or in part, or a denial of the petition. The Commissioner can provide a tentative response with an estimate on a time for a full response.

78. Gary Buehler, R.Ph., former Director of the Office of Generic Drugs ("OGD"), at CDER, noted that of forty-two (42) citizen petitions raising issues about the approvability of generic products, "very few...have presented data or analysis that significantly altered the FDA's policies." Despite this, it is standard practice for the FDA to withhold ANDA approval until it has completed its research into and response to a citizen petition.

79. Responding to a citizen petition strains the FDA's limited resources. Regardless of how frivolous a petition may be, the FDA must expend considerable resources researching the petition's scientific, medical, legal, and economic issues, delaying ANDA approval, even if a petition is later found to be baseless.

80. Frivolous petitions have become increasingly common and have caused anticompetitive effects as branded pharmaceutical manufacturers seek to manipulate the system to leech whatever remaining profit is left from a given pharmaceutical market. In many cases, citizen petitions have been filed relating to ANDAs that have been pending for over a year, long after the brand manufacturer received notice of the

ANDA filing. In these cases, the petition delays the ANDA approval while the FDA evaluates the citizen petition. In most cases, there is no reason for the brand manufacturer's delay in filing the citizen petition.

81. The FDA has acknowledged manipulation of the citizen petition review process. Former FDA Chief Counsel Sheldon Bradshaw recognized that during his tenure he had "seen several examples of citizen petitions that appear designed not to raise timely concerns with respect to the legality of scientific soundness of approving a drug application but that to try to delay the approval simply by compelling the agency to take the time to consider arguments raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before."

H. Patent Prosecution

82. Filing a patent application is an *ex parte* process for which the law imposes a duty of good faith, candor, and disclosure on the filing party.[40] This duty requires the filer, including his or her agents, attorneys, or anyone else involved in the prosecution, to disclose all material information on the patentability of the claims.

83. An applicant's intentional withholding of information known to be material to patentability with the intent to deceive the USPTO constitutes inequitable conduct and renders a patent unenforceable.

[40] *See* 37 C.F.R. § 1.56; Manual of Patent Examining Procedure § 2000.

84. The existence of prior art is material to patentability.[41] Prior art means that "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public" or "the claimed invention was described in a patent issued under section 151, or in an application for a patent published or deemed published under section 122(b). . . ."[42]

VI. CELGENE'S ANTICOMPETITIVE CONDUCT

A. Thalomid and Revlimid

85. In the mid-20th century, thalidomide was marketed as a sleeping pill and anti-morning sickness pill for pregnant women. Devastatingly, when consumed by pregnant women, thalidomide caused life-threatening fetal deformities and birth defects. Adverse effects also included nerve damage.

86. Thalidomide was thereafter banned worldwide, including in the United States. The U.S. ban was in place until July 16, 1998, when the FDA approved Celgene's December 20, 1996 NDA 20-785 for Thalomid. The FDA approved Thalomid only as a treatment for ENL, a form of leprosy.[43] But to mitigate fetal exposure to the drug, the FDA conditioned its Thalomid approval on Celgene's use of the System for Thalidomide Education and Prescribing Safety ("S.T.E.P.S.") distribution program, in which patients were required to review educational materials,

[41] *See* 35 U.S.C. § 102.

[42] 35 U.S.C. § 102(a)(1)-(2).

[43] Thalomid was later approved in 2006 to treat MM, subject again to Celgene's restricted distribution system.

register with the program, and agree to program restrictions. The FDA noted in its Thalomid NDA approval "[t]hat current restrictions strike a balance between the need to prevent fetal exposure to the drug and the need to make the drug available without extraordinary burdens on patients and prescribers."

87. In 2010, the FDA codified the REMS distribution program (which replaced S.T.E.P.S.). The FDA approved Celgene's supplemental application containing a proposed REMS program for Thalomid on August 3, 2010. As a condition of obtaining Thalomid or Revlimid, distributors, pharmacists, and recipient patients were required to enroll in the REMS program.

88. Celgene filed, prosecuted, and listed in the Orange Book one (1) patent for the Composition of Matter for Thalomid: the '012 patent, which was first filed with the USPTO in June 2003. Celgene filed, prosecuted and listed a total of fourteen (14) patents in relation to the S.T.E.P.S. and/or REMS programs for controlling Thalomid, and later Revlimid, distribution: the '501 patent, the '976 patent, the '432 patent, the '984 patent, the '763 patent, the '188 patent, the '720 patent, the '977 patent, the '784 patent, the '399 patent, the '018 patent, the '566 patent, the '886 patent, and the '531 patent, all of which were filed with the USPTO between August 1998 and August 2012.

89. Revlimid is an immunomodulatory drug that works against cancer cells by affecting the immune system. It is a thalidomide analogue manufactured and marketed by Celgene. Celgene submitted NDA 21-880 to the FDA, which provides for the use of Revlimid to treat patients with transfusion dependent anemia due to low or

intermediate-1 risk myelodysplastic syndromes associated with a deletion 5 q cytogenetic abnormality with or without additional cytogenetic abnormalities, on April 7, 2005. The FDA approved Revlimid on December 27, 2005. Celgene was granted exclusivity for Revlimid as it was a new chemical entity ("NCE"); exclusivity expired on December 27, 2010. Competition, absent anticompetitive misconduct, would normally begin immediately after Celgene's exclusivity expired.

90. Revlimid is subject to a REMS distribution program, RevAssist. The primary goal of the RevAssist program, approved by the FDA, is to prevent fetal exposure to Revlimid. The FDA noted in its December 27, 2005 letter to Celgene that RevAssist is "an important part of the post- marketing risk management for Revlimid."

91. In addition to the patents listed in the Orange Book, Celgene was issued numerous additional patents related to thalidomide and its analogs. According to 21 U.S.C. § 355(b)(1), NDA applicants shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. Despite not listing these patents, indicating a belief that an infringement claim could not reasonably be asserted, Celgene made frivolous infringement claims for these patents in response to ANDAs for lenalidomide, as discussed below.[44]

[44] Celgene also filed and prosecuted several additional patents that it did not list in the Orange Book. They are Patent Nos. 6555554 (the "'554 patent"), 7119106 (the "'106

92. Celgene also filed, prosecuted, and listed in the FDA Orange Book three (3) patents for the Composition of Matter for Revlimid: the '517 patent, which was first filed with the USPTO in July 1996, and the two polymorph patents, the '800 patent and the '217 patent, first filed with the USPTO in September 2004 and December 2008, respectively (the "Polymorph patents"). Celgene filed, prosecuted, and listed several patents in relation to the RevAssist program for controlling Revlimid distribution: the '501 patent, the '976 patent, the '432 patent, the '763 patent, the '188 patent, the '720 patent, the '977 patent, the '784 patent, the '886 patent, and the '531 patent, which were filed with the USPTO between August 1998 and August 2012. Celgene filed, prosecuted, and listed a total of ten (10) patents related to the dosage and methods of treatment for Revlimid: the '740 patent, the '569 patent, the '363 patent, the '929 patent, the '717 patent, the '095 patent, the '120 patent, the '498 patent, the '621 patent, and the '622 patent, filed with the USPTO between April 2003 and September 2014. Another patent, the '745 patent, was filed in 2006, and was part of a pattern by Celgene of prosecuting invalid and unenforceable patents in a bid to erect a "patent fortress" around its Thalomid and Revlimid monopolies.

93. Witness below a chart of Celgene's web of patents:

patent"), 6281230 (the "'230 patent"), 6767326 (the "'326 patent"), 7977357 (the "'357 patent"), 8193219 (the "'219 patent") and 8431598 (the "'598 patent").

Patent	Number	Date Filed	Date Issued	Expiration Date	Description	Drug(s)
Composition of Matter						
'517 Patent	5,635,517	24-Jul-96	3-Jun-97	4-Oct-19	Method of reducing TNF.alpha. levels with amino substituted 2-(2,6-dioxopiperidin-3-yl)-1-oxo-and 1,3-dioxoisoindolines	Revlimid
'012 Patent	7,230,012	30-Jun-03	12-Jun-07	9-Dec-23	Pharmaceutical compositions and dosage forms of thalidomide	Thalomid
Polymorph						
'800 Patent	7,465,800	3-Sep-04	16-Dec-08	27-Apr-27	Polymorphic forms of 3-(4-amino-1- oxo-1,3 dihydro- isoindol-2-yl)- piperidine-2,6-dione	Revlimid
'217 Patent	7,855,217	15-Dec-08	21-Dec-10	24-Nov-24	Polymorphic forms of 3-(4-amino-1- oxo-1,3 dihydro- isoindol-2-yl)- piperidine-2,6-dione	Revlimid

Patent	Number	Date Filed	Date Issued	Expiration Date	Description	Drug(s)
REMS						
'501 Patent	6,045,501	28-Aug-98	4-Apr-00	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	Thalomid Revlimid (Pomalyst)
'976 Patent	6,561,976	26-Sep-01	13-May-03	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	Thalomid Revlimid (Pomalyst)
'432 Patent	6,908,432	22-Jan-04	21-Jun-05	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	Thalomid Revlimid (Pomalyst)
'984 Patent	7,874,984	12-Apr-05	25-Jan-11	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	Thalomid

Patent	Number	Date Filed	Date Issued	Expiration Date	Description	Drug(s)
'763 Patent	8,204,763	13-Dec-10	19-Jun-12	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	Thalomid Revlimid (Pomalyst)
'188 Patent	8,589,188	17-May-12	19-Nov-13	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	Thalomid Revlimid (Pomalyst)
'720 Patent	6,315,720	23-Oct-00	13-Nov-01	23-Oct-20	Methods for delivering a drug to a patient while avoiding the occurrence of an adverse side effect known or suspected of being caused by the drug	Thalomid Revlimid (Pomalyst)
'977 Patent	6,561,977	27-Sep-01	13-May-03	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid Revlimid (Pomalyst)

Patent	Number	Date Filed	Date Issued	Expiration Date	Description	Drug(s)
'784 Patent	6,755,784	7-Mar- 03	29-Jun-04	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid Revlimid (Pomalyst)
'399 Patent	6,869,399	22-Jan-04	22-Mar-05	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid
'018 Patent	7,141,018	3-Jan-05	28-Nov-06	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid
'566 Patent	7,959,566	19-May-06	14-Jun-11	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid

Patent	Number	Date Filed	Date Issued	Expiration Date	Description	Drug(s)
'886 Patent	8,315,886	13-Dec-10	20-Nov-12	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid Revlimid (Pomalyst)
'531 Patent	8,626,531	22-Aug-12	7-Jan-14	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid Revlimid (Pomalyst)
Dosing						
'740 Patent	7,189,740	11-Apr-03	13-Mar-07	11-Apr-23	Methods of using 3- (4-amino-oxo-1,3- dihydro-isoindol-2- yl)-piperidine-2,6-dione for the treatment and management of myelodysplastic syndromes	Revlimid
'569 Patent	7,968,569	15-May-03	28-Jun-11	7-Oct-23	Methods for treatment of multiple myeloma using 3-(4- amino-1-oxo-1,3-dihydro-isoindol-2- yl)-piperidine-2,6- dione	Revlimid

Patent	Number	Date Filed	Date Issued	Expiration Date	Description	Drug(s)
'363 Patent	7,468,363	8-Apr- 05	23-Dec-08	7-Oct-23	Methods for treatment of cancers using 3-(4-amino-1- oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione	Revlimid
'929 Patent	8,741,929	19-Nov-09	3-Jun-14	8-Mar-28	Methods using 3-(4- amino-1-oxo-1,3- dihydro-isoindol-2- yl)-piperidine-2,6-dione for treatment of mantle cell lymphomas	Revlimid
'717 Patent	8,404,717	24-Mar-11	26-Mar-13	11-Apr-23	Methods of treating myelodysplastic syndromes using lenalidomide	Revlimid
'095 Patent	8,648,095	5-Jun-12	11-Feb-14	15-May-23	Methods for treating multiple myeloma using 3-(4-amino-1- oxo-1,3-dihydroisoindol-2-yl)-piperidine-2,6-dione in combination with proteasome inhibitor	Revlimid

Patent	Number	Date Filed	Date Issued	Expiration Date	Description	Drug(s)
'120 Patent	9,056,120	13-Mar-13	16-Jun-15	11-Apr-23	Methods of treating myelodysplastic syndromes with a combination therapy using lenalidomide and azacitidine	Revlimid
'498 Patent	8,530,498	8-Apr- 13	10-Sep-13	15-May-23	Methods for treating multiple myeloma with 3-(4-amino-1- oxo-1,3-dihydroisoindol-2-yl)piperidine-2,6-dione	Revlimid
'621 Patent	9,101,621	17-Apr-14	11-Aug-15	15-May-23	Methods for treating multiple myeloma with 3-(4-amino-1- oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione after stem cell transplantation	Revlimid
'622 Patent	9,101,622	10-Sep-14	11-Aug-15	15-May-23	Methods for treating newly diagnosed multiple myeloma 3- (4-amino-1-oxo-1,3- dihydro-isoindol-2- yl)-piperidine-2,6-dione in combination with dexamethasone	Revlimid

Patent	Number	Date Filed	Date Issued	Expiration Date	Description	Drug(s)
'745 Patent	7,435,745	26-Apr-06	14-Oct-08	31-Jul-19 (Estimate)	Methods and compositions for inhibition of angiogenesis	Thalomid (Not listed in Orange Book)

B. Celgene Abused Its REMS Program as a Pretextual Justification for Refusing to Sell Samples and Illegally Monopolized the Market

94. Both Thalomid and Revlimid are subject to REMS distribution programs that require healthcare providers and pharmacies to be certified in the S.T.E.P.S. or RevAssist programs, respectively, and require patients to be enrolled in S.T.E.P.S. or RevAssist. Prescribers and pharmacists must complete registration forms. Females of childbearing potential are required to take a pregnancy test twenty-four (24) hours prior to starting a course of Thalomid or Revlimid and at least every four (4) weeks during treatment. All prescribers are required to provide contraception and emergency contraception counseling with each new prescription. For every new patient, prescribers must submit to Celgene a signed Patient-Physician Agreement Form that identifies the patient's risk category. The prescriber then receives a letter confirming the patient's enrollment and the patient and prescriber receive an authorization number which is to be written on the prescription. The pharmacy must verify that each prescription has an authorization number that is valid for seven (7) days. The pharmacy must then call Celgene, obtain a confirmation number, and write this number on the

prescription. The prescription is then filled within twenty-four (24) hours. No more than a twenty-eight (28) day supply may be dispensed at one time.

95. RevAssist operates through specialty pharmacies. Originally, the S.T.E.P.S. program operated in all pharmacies. In 2006, however, Celgene began operating S.T.E.P.S. exclusively through specialty pharmacies. Alexis Tosti, Celgene's Market Research Analyst, noted that moving to a specialty pharmacy would "be a hurdle for generic companies," and that "[r]estricted distribution is more likely to keep thalidomide out of the hands of generic companies who need product to test against the generic being developed," in internal company emails in 2006.[45]

96. The first key to Celgene's monopolistic anticompetitive scheme was to prevent generic manufacturers from obtaining the necessary samples of Thalomid and Revlimid to perform the BE testing needed to file an ANDA.

97. Celgene abused its REMS program as a pretextual justification for withholding Thalomid and Revlimid samples from generic competitors. Among the manufacturers that Celgene refused to supply are Mylan Pharmaceuticals Inc. ("Mylan") between 2004 and the present, Lannett Company ("Lannett") in 2006, Exela Pharmsci, Inc. ("Exela") in 2006, Dr. Reddy's Laboratories ("Dr. Reddy's") in 2008 and 2009, Watson Laboratories, Inc ("Watson") in 2009, Teva Pharmaceuticals USA ("Teva") in 2009, and Sandoz Inc. ("Sandoz") in 2012. Celgene also entered into an exclusive supply agreement with a French thalidomide supplier to prevent Barr

[45] Exhibit to MSJ Opp., Dkt. No. 285-20.

Laboratories ("Barr") from obtaining that company's thalidomide active pharmaceutical ingredient ("API").

98. Celgene's improper use of the REMS program as a shield to refuse to provide samples is contrary to the FDAAA. FDAAA subsection f(8) states that "no holder of [a REMS- covered drug] shall use any element to assure safe use…to block or delay approval of… an [ANDA application]."[46]

1. Celgene's REMS Program is a Post-Marketing Distribution System

99. Celgene's REMS distribution programs are post-marketing, commercial distribution programs. Celgene's REMS protocols do not discuss drug manufacturers conducting business with one another in the pre-marketing, drug development phase. Nor do Celgene's REMS protocols discuss or prevent distribution of samples to drug manufacturers.

100. Generic manufacturers' safety protocols are not required to be FDA-approved for that manufacturer to purchase samples of a REMS-subject drug. Robert West, former Deputy Director of OGD, commented that "a generic manufacturer is not required to submit its protocols to the FDA before commencing bioequivalence studies."[47]

[46] 21 U.S.C. § 355-1(f)(8).

[47] Exhibit to MSJ Opp., No. 14-cv-2094 (D.N.J.), Dkt. No. 285-15 (all references to "MSJ Opp." Herein refer to case number 14-cv-2094).

101. Clinical and pre-approval studies are not governed by REMS. In an August 2012 meeting with Celgene, the FDA stated, "Celgene's REMS relates to a marketed situation and not a clinical trial where there is more control regarding administration of the product and the amount given is monitored and very limited."

102. A sample supply of a brand-name drug, including the API, is required to manufacture a generic equivalent. The API is used to conduct the required bio-studies and validation testing before the generic manufacturer submits its ANDA.

103. Due to Celgene's REMS program, generic manufacturers were unable to purchase Thalomid and Revlimid samples in the United States through normal wholesale distribution channels. They were therefore forced to seek to purchase the drugs directly from Celgene, with the FDA's endorsement.

2. Celgene Refused to Sell Samples

a. Celgene Refused to Sell Samples to Mylan

104. Celgene refuses to sell Thalomid and Revlimid samples to Mylan, the second-largest generic pharmaceutical manufacturer in the world.

105. Mylan began developing a generic thalidomide product on September 26, 2003. On October 27, 2003 Mylan requested OGD provide guidance on prospective BE studies. OGD provided the requested guidance within the following year.

106. On December 22, 2003, Mylan requested thalidomide API from API suppliers GYMA Laboratories of America, Inc. ("GYMA") and Antibioticos to manufacture its formulation of thalidomide. By March 11, 2004, Mylan received thalidomide API from Antibioticos.

107. In September 2004, after Mylan was unable to gain access to Thalomid samples, the FDA suggested Mylan contact Celgene to request samples. On October 5, 2004, Mylan wrote Celgene a letter through its attorneys requesting to purchase 2,500 Thalomid capsules to conduct BE studies. Celgene failed to respond. Mylan repeated its request on May 3, 2005. At the time, Mylan had already completed safety training sessions for the handling and testing of thalidomide.

108. In a letter dated June 21, 2005, Celgene explained that, pursuant to its S.T.E.P.S. program, Thalomid was not available through normal wholesale channels, and that it was against Celgene's policy to deal with third parties in the sale of Thalomid. Notwithstanding the above, Celgene did not have a single internal discussion finding it would be a violation of S.T.E.P.S. to provide Mylan with Thalomid for BE testing without FDA approval.

109. In internal emails from July 6, 2005, Celgene noted that "Mylan has had difficulty obtaining enough of Celgene's reference product to perform BE studies, so its ANDA submission is expected to be delayed until late in the third quarter of 2005."

110. On September 2, 2005, Mylan directly contacted Celgene and requested to purchase 3,360 Thalomid capsules to conduct BE testing. Mylan explained that the "FDA had recommended that we contact you directly to request a sample" of Thalomid for BE testing, and that "obtaining samples through other traditional channels is nearly impossible."

111. On October 20, 2005, Celgene replied, claiming that it needed additional time to consider the request and "to avoid fetal exposure."

112. On November 15, 2005, Mylan used an intermediary to again request that Celgene sell it Thalomid samples for BE testing.

113. By December 2005, Mylan completed its scale-up of its experimental thalidomide batch. Mylan had, by that time, captured two-years' worth of stability data. The only remaining step to submitting its ANDA was to conduct BE studies against the RLD.

114. On December 19, 2005, Celgene stated that it would need the FDA's approval to allow Mylan to purchase samples outside of the S.T.E.P.S. program: "[W]e recommend that you contact the FDA's [Division of Special Pathogen and Transplant Products] to discuss the importance of the S.T.E.P.S. program to them." Celgene claimed that if the FDA then "contacts us in writing and recommends that we violate our S.T.E.P.S. program by providing you with the quantity of THALOMID you request, we will further evaluate your request at that time."

115. Celgene's refusal to sell Thalomid to Mylan was not based on any real concern about the quality of Mylan's safety protocols. In an internal report created in 2003 at Celgene's request, Celgene admitted Mylan's patient monitoring system—already in place for another drug it was studying—was robust, comprehensive, and equivalent to the S.T.E.P.S. program.

116. Detailing the manufacturer's procedures, Celgene's report stated that Mylan's safety protocols "currently have very sophisticated patient monitoring systems for their respective clozapine products."[48]

117. Furthermore, the report stated "it can be observed that the clozapine requirements are as comprehensive as the S.T.E.P.S. program. Thus, Ivax and Mylan already have experienced [sic] with sophisticated monitoring systems."[49]

118. Next, Mylan requested FDA assistance to obtain the necessary Thalomid samples required for bioequivalence testing on January 11, 2006. In its letter, Mylan proposed protocols to ensure avoidance of fetal exposure.

119. By emails dated March 3, 2006, Mylan estimated a Thalidomide launch for May 2010.

120. On February 12, 2007, the FDA replied, requesting an investigational new drug application ("IND") or study protocol so that it could "ensure that all appropriate safeguards for a clinical investigation with thalidomide are in place," as a substitute for the S.T.E.P.S. program.

121. The FDA's response continued:

> It is the FDA's view that certain restrictions are needed to ensure safe use of the drug; however, it is not the agency's intention to permit the restrictions of the S.T.E.P.S. program to prevent manufacturers of generic drugs from obtaining Thalomid for use in the bioequivalence testing necessary to obtain approval of an abbreviated new drug application for a thalidomide product. The agency believes that such bioequivalence studies can be conducted

[48] Exhibit to MSJ Opp., Dkt. No. 286-1.

[49] *Id*.

> safely under either an IND or in circumstances that provide alternative assurance of patient safety. To ensure that the intention of Congress in enacting the generic drug approval provisions in section 505(j) is not frustrated by the terms of the S.T.E.P.S. program, FDA has notified Celgene that the agency intends to exercise its enforcement discretion to permit Celgene to provide to another drug manufacturer (or its agent) 500 units of Thalomid (including 200 units for the purpose of conducting bioequivalence (including dissolution) testing and 300 units for a limited number of retained samples) when Celgene has received confirmation in writing from the sponsor, its agent, or FDA that the sponsor of the study either has an IND in effect for the study or has otherwise provided the agency with sufficient assurance that the bioequivalence study will be conducted in such a manner as to ensure the safety of the subjects.

122. On May 1, 2007, Mylan produced to the FDA its proposed thalidomide safety protocols, which the FDA reviewed, found "acceptable," and so notified Mylan on September 11, 2007.

123. On November 16, 2007, Mylan notified Celgene of the FDA's approval, which directly addressed Celgene's pretextual justification for not providing samples. Celgene's senior executives and officers all admit that the FDA is the ultimate authority on setting safety standards. Yet Celgene continued to deny Mylan's and others requests for drug samples for BE testing, using pretextual and obviously flawed safety concerns as its chief justification.[50]

[50] On April 21, 2000, the FDA sent Celgene a "Warning Letter" stating that "Celgene has engaged in promotional activities that state or suggest that Thalomid is safe and effective for use in treating multiple myeloma." With no generics on the horizon, Celgene was willing to play fast and loose with the safe distribution of Thalomid so long as it ensured increased prescription volume and increased profits.

124. Undeterred, Mylan continued to make requests over the next three (3) years, including on December 4, 2007. Celgene continued to refuse to produce Thalomid samples, using delay tactics including requiring Mylan to produce burdensome, irrelevant, and duplicative information. Meanwhile, Celgene internally admitted that another prospective ANDA filer's request was "deficient in a way that the Mylan request is not."

125. On January 8, 2008, Celgene wrote Mylan requesting more information. Mylan responded on February 25, 2008 writing that it was prepared to provide all requested information and enclosed a confidentiality agreement. Celgene and Mylan negotiated the confidentiality agreement until June 24, 2008, when Celgene sent Mylan the executed agreement. Mylan sent Celgene another letter providing even more information and provided Celgene with proof of liability insurance covering any instances of injury relating to drug's misuse, and further provided an indemnity contract.

126. This contract, which was extensively negotiated, agreed to hold Celgene harmless in the event of any injury or misuse.

127. Celgene wrote Mylan on August 1, 2008 that it was reviewing Mylan's documentation. Celgene's then-Regulatory Counsel testified that as of March 4, 2011, no "business people" at Celgene reviewed any of Mylan's documentation. Confoundingly, Celgene served an interrogatory response in an FTC investigation that two former CEOs, Sol Barer and Robert Hugin, "made the decisions on behalf of Celgene regarding Celgene's responses to pharmaceutical companies requesting to

purchase Revlimid and Thalomid with legal advice from Celgene's Deputy General Counsel and then-Regulatory and Compliance Counsel." The referenced in-house counsel later testified in a separate litigation that they did not have any input into the requests, could not recall reviewing a single response to one of the information requests submitted to Celgene, or sitting in a meeting in which a response to a prospective ANDA filer's request was discussed. Upon information and belief, Celgene's interrogatory response to the FTC contained false information.

128. Celgene wrote Mylan in a June 24, 2009 letter that there were "outstanding issues" with the information Mylan provided and requested nine (9) additional categories of information. An internal Celgene email dated May 22, 2009 contained a project titled "Thalidomide Multiple Myeloma." The summary of the project stated "***A generic thalidomide application was successfully delayed*** until at least June '09 in the USA. ***Celgene may further extend its exclusivity in the USA by using bioequivalence as a generic defense strategy***…." (emphasis added). Celgene's own emails show that it was never truly concerned with the safe distribution of its drugs, but rather used safety as a pretextual justification to prevent generic competition.

129. Celgene's refusal to sell Mylan samples, despite the existence of liability insurance and an indemnity contract, is further evidence Celgene was unwilling to negotiate in good faith with generic manufactures to provide the requested drugs. A federal court previously found, based on these facts, that one could reasonably infer "that Celgene had no objectively legitimate business justification for not selling Mylan

samples of Thalomid or Revlimid samples after FDA approval of Mylan's study protocols."

130. Mylan estimates that had Celgene provided it with Thalomid samples in 2006, it would have filed a Paragraph IV Certification, Celgene would have initiated a patent infringement litigation and Mylan could have ultimately entered the thalidomide market in the third quarter of 2010. But for Celgene's conduct, Mylan would have launched a generic competitor to Thalomid at some point in time prior to its actual entry.

131. By June 2007 Mylan began to develop its generic Revlimid. In internal emails from September 2007, Mylan planned to file its ANDA on December 27, 2009, was actively sourcing raw materials, had opinions on the blocking compound patents and planned to design around the formulation patent.

132. In early 2009, Mylan endeavored to purchase lenalidomide supplies to manufacture a generic version of Revlimid. Celgene engaged in more (of the same) delay tactics, causing Mylan to cease development efforts at various points while it attempted to procure Revlimid samples. Mylan manufactured its final lenalidomide formulation in June 2015.

133. In June 2010, in response to FTC interrogatories, Celgene explained to the FTC that "Celgene has decided not to sell REVLIMID at the present time to manufacturers."[51]

[51] Exhibit to MSJ Opp., Dkt. No. 286-4.

134. Over two years later, through its counsel, Celgene wrote to the FTC that it was willing to "continue selling Thalomid and begin to sell Revlimid to drug companies, branded or generic, in quantities authorized by the FDA sufficient to conduct bio equivalence studies for the purpose of preparing an Abbreviated New Drug Application [ANDA] with the FDA."[52] Despite its representation that it would "continue" to sell Thalomid, Celgene, at no point prior to this email, ever sold Thalomid to generic drug companies to support BE studies for the purpose of preparing ANDAs. Celgene's letter continued: "[Celgene would] seek to set appropriate conditions with the FDA for the sale of Revlimid similar to those it has set for the sale of Thalomid…."

135. On August 14, 2012, Celgene wrote to the FDA claiming that the FDCA does not require an RLD sponsor to provide drug product to a proposed ANDA filer, and that the FDA does not have authority to mandate any such requirement. Celgene even threatened that "any sale of Revlimid to a generic manufacturer will not be effectuated unless and until the FTC and the State of Connecticut Attorney General agree to close their investigation."[53]

136. On May 1, 2013, Mylan requested to purchase Revlimid samples from Celgene at market value. On May 14, 2013, Celgene wrote to Mylan that it would sell

[52] *Id*.

[53] Exhibit to MSJ Opp., Dkt. No. 285-15.

Revlimid to Mylan upon Celgene's review of Mylan's request and supporting documentation.

137. While not required to do so, Mylan sought FDA approval of its proposed safety protocols to avail itself of any assistance the FDA might be able to offer in procuring Revlimid samples. The FDA approved Mylan's protocols on July 29, 2013.

138. On March 11, 2014 Mylan wrote to Celgene explaining that it received all necessary approvals from the FDA. Celgene continued to refuse to provide samples, even, once again, after being informed of FDA approval for the proposed BE testing and safety protocols.

139. On March 20, 2014, Celgene again wrote to Mylan refusing to sell Mylan Revlimid samples. Exasperated with Celgene's tactics, Mylan brought a suit on April 3, 2014 against Celgene under federal and state antitrust laws for its anticompetitive tactics to maintain monopoly power in the market for Thalomid and Revlimid.

140. Mylan alleged that Celgene cited safety concerns as a pretext for its continued refusal to provide samples of Thalomid and Revlimid, and that Celgene used a "playbook of obstruct[ion]" and "gam[ed] the regulatory system."[54]

141. On May 19, 2014, the FDA notified Celgene that it accepted Mylan's submitted lenalidomide safety protocols and reiterated the FDCA's prohibition of using REMS to prevent ANDA filers from accessing drug samples.

[54] *Mylan Pharma Inc. v. Celgene Corp.*, No. 14-cv-2094 (D.N.J. Apr. 3, 2014), Dkt. No. 1 ¶8.

142. The FTC filed an amicus brief in support of Mylan's suit against Celgene. The FTC noted that the FDAAA was intended to prevent brand-name manufacturers from using REMS programs to impede generic competition, as Celgene was doing with Thalomid and Revlimid.

143. Further, in August 2012, the FTC sent counsel for Celgene an email detailing "a number of questions [raised] by the Bureau of Competition and the staff of the Connecticut Attorney's General office."[55]

144. These concerns included questions surrounding why Celgene had yet to sell samples of Thalomid to those requesting it, despite receiving explicit authorization from the FDA to do so.

145. The letter also questioned what else Celgene would need to receive in order to authorize the sale of Revlimid to generic manufacturers: "in the interest of advancing our discussions and trying to reach a prompt resolution with you, we propose the FTC and Celgene meet together with the FDA . . . to discuss what Celgene thinks it needs from the FDA in order to be able to make prompt sales to generic firms."[56]

146. The FTC's Bureau of Competition ("BOC") followed up on this letter with another round of correspondence in February 2013.

[55] Exhibit to MSJ Opp., Dkt. No. 285-16.

[56] *Id*.

147. In a letter to Celgene's counsel, the BOC stated "that there is a lot of concern here-at both the Bureau and Commission levels- about the time it has taken for your client to [redacted] of Revlimid capsules for bio-equivalence testing…the Commission's patience is wearing thin. We have reached a point where the staff may be instructed in the very near future to commence litigation."

148. Counsel for Celgene quickly forwarded this email Celgene executives.

149. Most of Mylan's claims survived Celgene's motion to dismiss. Celgene subsequently filed its motion for summary judgment. On October 3, 2018, Celgene's motion was granted in part and denied in part. A final pre-trial conference was set for March 19, 2019. In August 2019, Celgene agreed to pay Mylan $62 million to settle the lawsuit. The parties did not disclose the terms of the settlement, such as whether it includes any agreement restricting Mylan's ability to launch generic versions of Thalomid or Revlimid, or whether Celgene agreed to not launch products that would compete against certain products manufactured by Mylan.

150. One of Mylan's expert witnesses in that litigation, Paul J. Jarosz, Ph.D., testified that Mylan's development process was typical for the pharmaceutical industry and that "[h]ad Mylan been able to purchase Thalomid so that it could dose its bioequivalence studies and receive an approval for its generic drug application, Celgene's '012 patent and claim 2 of its '327 patent would have not have prevented

Mylan from launching its generic thalidomide product as the claims are invalid due to prior art and/or Mylan's formulation does not infringe them."[57]

151. Regarding generic Revlimid, Dr. Jarosz stated that "based on the simple nature of Revlimid and Mylan's previous experience developing thalidomide, it appears that Mylan could have developed and filed an application for generic lenalidomide product by December 27, 2009."[58]

152. Dr. Jarosz's report confirms that the inability of generic drug manufactures to bring versions of Thalomid and Revlimid to market were not due to internal issues or manufacturing defects. Instead, his report reinforces the fact that the only barrier to entry in the market was Celgene's conduct.

153. On information and belief, Mylan has yet to receive Revlimid samples. Celgene's continued refusal to provide samples of Thalomid and/or Revlimid only further elucidates that Celgene's refusal based on safety concerns was and continues to be a conveniently fabricated excuse to frustrate competition.

i. Mylan Developed Strong Safety Protocols

154. In September 2011, Sofgen Pharmaceuticals ("Sofgen") contacted Mylan regarding the potential purchase of Amnesteem for BE testing.

155. Like lenalidomide and thalidomide, Amnesteem is a known human teratogen, and was under FDA restriction for sale and delivery.

[57] Exhibit to MSJ Opp., Dkt. No. 285-21.

[58] Id.

156. Sofgen knew of these restrictions and reached out to the FDA prior to contacting Mylan to receive an assurance its iPLEDGE safety restrictions were acceptable and allowed it to receive a drug known to be a human teratogen.

157. The FDA sent Sofgen a letter in response, confirming Sofgen's iPLEDGE procedures were adequate under current FDA guidelines.

158. In response to receiving FDA approval, Mylan and Sofgen entered into successful negotiations surrounding Sofgen's purchase of Amnesteem samples from Mylan. This included the drafting of an indemnity agreement, discussions on the purchase price, and the method for payment and delivery. The sale was completed, and samples were delivered to Sofgen in Spring 2012.

159. Unlike Celgene, Sofgen and Mylan's discussions surrounding the purchase of Amnesteem show that receiving an approval letter from the FDA removes any perceived roadblocks to sharing a drug sample for BE testing.

160. Mylan's contract with Sofgen shows the process for obtaining generic drug samples can be completed in a short timeframe, and without the unnecessary and burdensome documentation Celgene requested from numerous generic manufacturers.

161. Further, another expert hired by Mylan in its lawsuit against Celgene, Jeff Fetterman, opined that Mylan's experience with the REMS process was robust and extensive, and it would have no issues implementing one for generic thalidomide and lenalidomide.[59]

[59] Exhibit to MSJ Opp., Dkt. No. 286-2.

162. As Mr. Fetterman stated in his report, "Mylan has extensive experience developing, implementing, and managing risk management programs, including several REMS programs with the same or similar restrictions and requirements as the S.T.E.P.S. and RevAssist programs."[60]

163. Mr. Fetterman continued and stated "[i]f Celgene had provided brand samples to Mylan and cooperated in developing a shared REMS program for thalidomide, the SS REMS development and FDA approval likely would have taken 18 to 24 months. Furthermore, this estimate may be conservative, as an alternative parallel agreement to sign onto the S.T.E.P.S. program would have taken even less time, possible in as few as 12 months. All of this work could have begun in advance of Mylan's ANDA approval…."[61]

164. Mr. Fetterman's report details further how Celgene's refusal to provide drug samples on the basis of noncompliance with REMS procedures was a misdirection and stall tactic not based in truth or fact.

b. Celgene Refused to Sell Samples to Exela

165. On May 31, 2006, Exela contacted Celgene and informed it of Exela's intention to file an ANDA for Thalomid. Exela stated it was having difficulty obtaining samples of this drug from other channels, much like the other generic manufactures who had contacted Celgene. Exela requested a proposal for purchase within 10 days.

[60] Id.

[61] Id.

166. On June 27, 2006 Exela sent a follow up letter to Celgene again requesting to purchase Thalomid samples. In its letter, Exela noted the 10-day window for a purchase proposal had lapsed despite being received the day after it was sent.

167. On September 11, 2007, OGD wrote to Exela that its "proposed bioequivalence study protocol comparing Thalidomide Capsules, 200 mg to [Thalomid] is acceptable…."

168. On December 11, 2007, OGD Director Gary J. Buehler sent a letter to Celgene's internal regulatory counsel, Kerry Rothschild stating that "FDA has reviewed the bioequivalence protocol submitted…on behalf of Exela and has received sufficient assurance that the bioequivalence study will be conducted in such a manner as to ensure the safety of the subjects and has determined that Celgene may provide Exela with 500 units of Thalomid ***as indicated in FDA's letter to you dated February 8, 2007*** for the purposes of conducting an in vivo bioequivalence study and in vitro dissolution testing." (emphasis added).

169. On January 8, 2008, counsel for Celgene contacted counsel for Exela regarding the Thalomid purchase request.

170. In a response almost identical to ones given to other generic manufactures, Celgene stated it did not believe it was obligated to turn over any samples. However, it continued that if Exela were to comply with a list of 10 demands for information, including, for example, proof of liability insurance and a history of product loss due to improper handling or tracking, Celgene would then "reconsider" its denial. Upon

information and belief, Celgene never provided Exela with the requested samples of Thalomid.

c. Celgene Refused to Sell Samples to Lannett

171. On September 6, 2006, Lannett wrote a letter to the FDA requesting BE recommendations regarding thalidomide capsules.

172. The FDA's OGD responded to Lannett's letter on February 12, 2007. The OGD stated that "it is not the agency's intention to permit the restrictions of the S.T.E.P.S. program to prevent manufacturers of generic drugs from obtaining Thalomid for use in the bioequivalence testing necessary to obtain approval of an abbreviated new drug application for a thalidomide product."

173. The OGD commented that, to ensure Congress' intentions in enacting the Generic Drug Approval Provisions in Section 505(i) are carried out, the "FDA has notified Celgene that the agency intends to exercise its enforcement discretion to permit Celgene to provide to another drug manufacturer (or its agent) 500 units of Thalomid… for the purpose of conducting bioequivalence testing."

174. The FDA did so notify Celgene, on February 8, 2007, that "a study protocol would be reviewed by FDA to ensure that all appropriate safeguards for a clinical investigation with thalidomide are in place" if a proposed generic manufacturer wished to conduct BE studies. FDA explained that it would "exercise its enforcement discretion to permit Celgene to provide to another drug manufacturer (or its agent) 500 units of Thalomid for the purpose of conducting [BE] testing, when Celgene has received confirmation in writing from the sponsor, its agent, or FDA that the sponsor of

the study either has an IND in effect for the study or has otherwise provided the agency with sufficient assurance that the [BE] study will be conducted in such a manner as to ensure the safety of the subjects."

175. The FDA's letter also requested Celgene submit a supplement to its own Thalomid NDA to the same effect. Celgene failed to submit this supplement, evidencing its own disregard for safety (among other things).

176. Nevertheless, Celgene's then-regulatory counsel Kerry Rothschild testified that the FDA's February 8, 2007 letter did not fully assuage Celgene's worry that a fetal exposure and birth of a baby with thalidomide-recognizable defects would have consequences to the value of Celgene's business.[62] Celgene Chief Executive Officer, Mark Alles, testified in 2016 that of the small number of fetal exposures to Thalomid between its development and 2016, the exposures "had minimal impact on the business as far as I know…."[63]

177. Celgene's Senior Vice President and Head of Global Drug Safety did not raise any alarm when reporting to Celgene's senior executives that a patient opted to continue her pregnancy to term despite fetal exposure to thalidomide in an email dated March 8, 2010. Celgene's CEO responded to the email in a similarly unalarmed manner.

[62] Exhibit to MSJ Opp., Dkt. No. 285-1 at 36-27.

[63] Exhibit to MSJ Opp., Dkt. No. 286 at 185-186.

178. In a July 26, 2007 letter to Celgene, Arthur P. Bedrosian, President and CEO of Lannett, wrote:

> In order to complete our bio-study, the FDA has instructed us to purchase 250 Thalomid 200 MG Capsules from you. We kindly request information as to how to best carry out this transaction. We will be happy to supply a purchase order once you provide us with the total product cost. Submitted with this document, you will find the appropriate licenses necessary for us to purchase the product from you. We kindly ask that you inform us of any additional information you will need to complete this transaction.

179. Upon information and belief, in September 2007, Lannett faxed to Darnell Ragland, Manager, Customer Care of Celgene, a requested copy of the February 12, 2007 FDA letter, which authorized Lannett to acquire Thalomid supplies from Celgene.

180. Celgene continued to refuse Lannett's request. Celgene even went as far as actively screening any communication from Lannett directed towards Celgene regarding requests for samples of Thalomid.

181. In a September 28, 2007 internal email (only made publicly available in redacted form in 2018), a Celgene training alert ordered employees "**DO NOT PROCESS THE ORDER**" (emphasis in original) if a generic company calls or writes requesting to order Thalomid. Instead, the call center employees were directed to log the call, advise that a management team member would return the call, and to never transfer the call to someone higher up.

182. Employees were further instructed to forward any correspondence via fax to one of their supervisors.

183. Then, on October 18, 2007, Lannett wrote a letter to Mr. Ragland reiterating Lannett's request so that it could conduct BE testing needed to obtain approval to market its generic thalidomide.

184. On January 8, 2008, Celgene advised Lannett that it would not provide samples of Thalomid to Lannett. Rather, Celgene requested Lannett produce voluminous and unnecessary documentation in order for Celgene to "reconsider" the request.

185. On January 14, 2008, Lannett filed a complaint against Celgene seeking, among other things, mandatory injunctive relief requiring Celgene to provide samples of Thalomid as contemplated by the February 12, 2007 FDA letter.[64] The case was dismissed without prejudice.

186. Lannett then provided almost all of the information that Celgene requested except its highly confidential FDA Form 483 inspection reports, which relate to the routine inspection of manufacturing facilities, given that the Thalomid samples Lannett requested would not be used for manufacturing, but rather for BE studies that it would perform overseas.

187. Lannett submitted its proposed study for FDA review, and received approval on August 11, 2008.

[64] Lannett Company, Inc. v. Celgene Corp., No. 08-cv-0233. (E.D. Pa.).

188. Lannett refiled its complaint on August 15, 2008 alleging violations of the Sherman Act and seeking injunctive relief. Celgene filed its motion to dismiss on November 4, 2008. The motion was denied on May 13, 2010.

189. Celgene reached a confidential settlement with Lannett in 2011.

190. In its 2012 Annual Report, Lannett stated that "a sizable portion of our fiscal 2013 R&D budget is earmarked for two large market opportunity projects, C-Topical and Thalidomide." Its 2013 Annual Report stated that Lannett "successfully passed critical milestones for submitting a product application for Thalidomide." As discussed below, Lannett eventually filed a thalidomide ANDA in late 2014.

191. Upon information and belief, the settlement between Celgene and Lannett may have contained anticompetitive terms, such as a promise to delay submission of the ANDA.

192. The anticompetitive effect of Celgene's conduct was to delay Lannett's ANDA. Though Lannett began requesting Thalomid samples in 2006, it was unable to obtain such samples due to Celgene's delay until after December 2011 and did not file its ANDA until 2014, at which time Celgene filed a sham patent litigation, discussed below, all to delay Lannett's thalidomide product.

d. Celgene Refused to Sell Samples to Dr. Reddy's

193. Dr. Reddy's is a prescription drug manufacturer based in Telengana, India. It has been developing generic prescription drugs in the United States since 1994.

194. Dr. Reddy's requested samples of Revlimid from Celgene to perform BE testing in August 2008. Celgene did not reply to this request.

195. Dr. Reddy's repeated its request in December 2008. Celgene offered a single sentence reply in January 2009: "Celgene has no obligation to supply Dr. Reddy's with Revlimid and declines to do so."

196. In their request to Celgene, Dr. Reddy's assured Celgene any testing it performed would comply with FDA guidelines, using methods similar to Celgene's REMS program known as RevAssist to insure proper handling of the subject drugs.[65]

197. Dr. Reddy's filed a citizen petition with the FDA in June 2009, alleging that Celgene was refusing to provide samples to a generic drug manufacturer to perform BE testing.

198. Celgene once again premised its refusal on its REMS program, despite the FDA's previous guidance.

199. In 2016, Dr. Reddy's filed an ANDA for a generic lenalidomide product. As discussed below, Celgene then sued Dr. Reddy's claiming patent infringement.

e. Celgene Refused to Sell Samples to Teva

200. Teva requested a total of 5,000 Capsules in 5, 10, 15, and 25 mg dosages of Revlimid from Celgene to perform BE testing in March 2009.

201. In their letter to Celgene, Teva stated that its "…procedures for conducting any required testing involving lenalidomide and the Revlimid drug product provided by Celgene Corporation will fully comply with FDA requirements. Teva's controls with respect to lenalidomide will be comparable to the RevAssist program."

[65] Exhibit to MSJ Opp., Doc No. 285-6.

202. In April of 2009, Celgene responded to Teva's request, and in a one (1) sentence reply, stated "[t]his letter is to inform you that your request for 5,000 capsules of REVLIMID (lenalidomide) in varying strengths is declined."

203. Celgene's refusal to provide Teva with samples of Revlimid follows a similar course of conduct with other generic pharmaceutical companies.

f. Celgene Refused to Sell Samples to Watson

204. In June of 2009, much like the other generic manufacturers described above, Watson contacted Celgene to acquire samples of Thalomid and Revlimid for BE testing.

205. In its request, Watson assured Celgene the process by which it would handle the samples of these drugs would fully comply with a restricted distribution system similar to RevAssist.

206. Furthermore, Watson assured Celgene that FDA guidelines would be followed and no drug would be distributed in violation of these guidelines, which would be unlikely to happen given Watson's experience and expertise in the generic drug manufacturing market.

207. In July 2009, despite Watson's assurances that the requested samples would be handled in a safe, effective, and FDA-compliant manner, Celgene responded with a list of 10 pieces of evidence and documentation Watson would need to provide before Celgene would consider Watson's request. Celgene indicated it would respond to Watson's request for Revlimid in a separate letter.

208. Tellingly, Celgene did not say satisfying these 10 requirements would facilitate a prompt sale of the samples, merely that at that time Celgene would "consider" it.

209. Upon information and belief, like the generic manufacturers before and after, Watson was unable to obtain the samples of Thalomid and Revlimid it requested, with no logical reason provided.

g. Celgene Refused to Sell Samples to Sandoz

210. In May of 2012, much like the other generic manufacturers described above, Sandoz contacted Celgene attempting to acquire samples of Thalomid and Revlimid for BE testing.

211. In response, Celgene refused to provide the samples, and instead listed nine (9) prerequisites Sandoz had to satisfy before it would consider selling the requested samples.

212. These prerequisites included Sandoz provide "Proof of liability insurance sufficient to cover events associated with thalidomide and lenalidomide", "[p]olicies for biohazard handling, disaster recovery plans as well as the storage and use of teratogenic products", and "[w]ritten confirmation that an IND is in effect or a study protocol . . . has been approved by the FDA."

213. Like its correspondence with other generic manufacturers wishing to obtain drug samples, Celgene referenced the REMS procedures as a reason it could not immediately supply Sandoz with samples, despite FDA approval of Sandoz's procedures.

214. Upon information and belief, like the generic manufacturers before it, Sandoz was unable to obtain the samples of Thalomid and Revlimid it requested.

h. Celgene Prevented Barr from obtaining API Supply from Seratec

215. After the FDA approved Celgene's Thalomid, Barr, a generic drug manufacturer, sought to develop a generic version of thalidomide. As discussed, to market a generic drug, FDA requires a generic manufacturer to file an ANDA application detailing the proposed drug. The ANDA filer must identify its API supplier in its application. The API supplier must submit a Drug Master File ("DMF") to the FDA, which is evaluated with the ANDA.

216. In approximately 2004, Barr succeeded in procuring thalidomide API from Seratec S.A.R.L. ("Seratec"), a French supplier, to develop a generic version of Thalomid by September 2005. Barr submitted its ANDA to the FDA and was waiting to receive a DMF letter from Seratec.

217. Barr's ANDA proposed a skinny label, only seeking approval for ENL, and not MM.

218. While Barr and Seratec were finalizing negotiations, Celgene and Seratec entered an exclusive supply agreement for thalidomide. Upon information and belief, Celgene demanded exclusivity from Seratec to interfere with Barr's ability to market generic Thalomid. The exclusivity agreement was not because Celgene required all the API that Seratec could produce. Seratec, therefore, could no longer supply Barr with

its thalidomide API. The FDA did not accept Barr's ANDA due to deficiencies in providing a DMF from Seratec.[66]

219. Consequently, Barr was forced to find a different thalidomide supplier and repeat testing, causing it great expense and delay in launching generic thalidomide.

220. On February 27, 2006, Celgene's competitive intelligence firm, GBMC, updated Celgene that Barr completed BE testing and was planning on filing a thalidomide ANDA in the second quarter of 2006 using API from either Antibioticos of Italy or Shilpa of India. GBMC noted that "[t]hese companies were being used to replace the Seratec API that Barr originally was using for its ANDA."

221. After securing a new supplier and performing new BE studies and validation testing, Barr submitted its thalidomide ANDA on September 22, 2006. The ANDA showed that Barr's generic product was bioequivalent to Celgene's Thalomid. The FDA accepted Barr's thalidomide ANDA for filing on December 4, 2006.

222. Celgene subsequently initiated a patent infringement lawsuit against Barr for its thalidomide ANDA, as discussed more thoroughly below, initiating an automatic 30-month stay of FDA's approval of Barr's ANDA.

[66] It was unclear to Celgene how Barr acquired Thalomid samples for BE testing in 2005. In Celgene's response to interrogatories in a separate litigation , Celgene noted "Celgene informed the FDA of its belief that Barr had acquired Thalomid capsules from a pharmacy in Astoria, New York in violation of the requirements of the S.T.E.P.S. program. The FDA informed Celgene that it did not intend to 'recapture' these capsules from Barr, and that the manner in which Barr obtained Thalomid for use in its bioequivalency testing would not affect FDA's consideration of any subsequent ANDA with respect to thalidomide that Barr might file."

223. GBMC predicted that Barr could be expected to receive FDA approval of its thalidomide ANDA in the first quarter of 2009.

224. In a May 2009 email between executives at Celgene, which contained the minutes of a previously held internal meeting, these executives discussed Barr's attempt to market generic thalidomide in the USA.[67]

225. According to the minutes of the meeting: "Dianne Azzarello Regulatory Canada discussed possible ways to defend Thalidomide against generic infiltration in the USA. From her experience in working with generic drug providers she is of the opinion that we are able to use bioequivalence as generic defense strategy. The team supports this notion. If generic companies have to effectively prove that they are at least equivalent to what Celgene has to offer including Celgene's RiskMap before making product available on the market."

226. They also discussed paying for research and publishing research papers stating generic manufacturers' version of Thalomid were not bioequivalent: "Diane Azzarello and Henry Lau are working with Dr. Iain McGilveray who will publish a paper providing evidence that many other formulations of thalidomide available are not bio equivalent to Celgene's Thalomid. We may also include our simple formulation and its chemical properties as rationale. Funding for this publication is estimated to be $40k $60k."

[67] Exhibit to MSJ Opp., Dkt. No. 284-4.

227. These internal discussions are further evidence Celgene was not negotiating the sale of sample drugs to generic manufactures in good faith and were instead employing delay tactics at every turn to resist supplying generic manufactures with the requested drugs.

3. Celgene's Safety Concerns Were Pretextual

228. While Celgene refused to supply any potential ANDA sponsor the necessary and required samples of Revlimid and/or Thalomid based on safety concerns, it authorized its competitive intelligence firm to purchase, handle, and transfer thalidomide with no safety training required.

229. In 2003, Celgene authorized GBMC to purchase thalidomide API from a European supplier, Alan Pharmaceuticals. In fact, GBMC was authorized by Celgene to use undercover purchases to obtain samples of thalidomide API from various API suppliers. In an undated letter, GBMC detailed the sequence of events it used to acquire, at Celgene's request, thalidomide samples outside the normal chains of distribution. This sequence included falsifying prescriber names and permitting GBMC (a non-pharmaceutical company with no experience in handling teratogenic drug product) to handle thalidomide samples, all without a formal tracking mechanism. Celgene's Senior Director of Market Research testified in a previous litigation that he did not notify Celgene's legal department of these undercover purchases, that Celgene did not do background checks on individuals that would be handling the drug product, and that he could not recall whether the purchased product was in its proper packaging when Celgene received it, or who at Celgene received it.

230. The Celgene authorized-transactions did not comport with any safety protocol.

231. Celgene willingly and frequently provided access to Thalomid and Revlimid to non-competitor research organizations, outside the REMS process and without FDA guidance or approval for the safe handling of the drug products, for the purpose of conducting clinical studies.

232. Celgene provided Revlimid for at least 3,600 different research and investigational studies that all operated outside the REMS process. Celgene similarly provided Thalomid for over 100 investigator-initiated trials ("IIT").[68]

233. For example, Celgene provided Thalomid and Revlimid to the Johns Hopkins School of Medicine for clinical trials and provided Revlimid to Intergroupe Francophone du Myelome, University Hospital of Toulouse, and Groupe Francophone Des Myelodysplasies, as well as the National Cancer Institute, Eastern Cooperative Oncology Group, Mayo Clinic, and MD Anderson Cancer Center in Houston, TX.

234. An IIT process is initiated when an investigator submits a Letter of Intent ("LOI") outlining a proposal. The brand company, here Celgene, then reviews the proposal. Celgene testified that it tried not to review the full protocol, but rather would typically review a simplified synopsis, along with the nature of the request, the budget, and the amount of drug requested. The request, typically adjudicated within two (2)

[68] IITs are clinical studies initiated and managed by non-pharmaceutical company researchers, such as individual investigators, institutions, collaborative study groups, cohorts or physicians.

months, does not require in-house counsel assistance. Celgene has never denied an IIT proposal due to fetal exposure safety concerns.

235. After approving an IIT proposal, Celgene works with the investigator to draft a study protocol and consent form which then is submitted to the FDA for approval. Celgene had admitted that FDA's approval gives Celgene confidence in the safety of the trial. Celgene then supplies Revlimid or Thalomid to the investigator to initiate the study.

C. Celgene Commits Fraud on the USPTO and Files Sham Litigations Seeking to Enforce its Fraudulently Obtained Patents

236. Even when a generic manufacturer managed to obtain a sample of Thalomid or Revlimid, Celgene was still able to block them from the market by obtaining numerous redundant patents related to the composition, and plans for safe distribution, of Thalomid and Revlimid.

237. These types of patents generally claim the use of registries to register patients, prescribers, and pharmacies, testing and regular re-testing the patient for signs of harmful side effects associated with the drug (including pregnancy testing), counseling patients about the risks associated with the drug, limiting the dispensed amount of the drug, and prescribing and dispensing the drug after analyzing the risk and determining that it is acceptable.

238. The patent on Celgene's active ingredient in Revlimid, the '517 patent, expired in 2019. The last of Revlimid's patents listed in the Orange Book, the '800 Polymorph patent, expires in 2028.

239. Celgene, armed with its fraudulent patents, serially filed sham patent infringement lawsuits and citizen petitions against any Paragraph IV ANDA filer. Through these serial sham litigations, Celgene was able to successfully, and illegally, block generic entrants from the Revlimid and Thalomid markets.

1. Celgene's Fraudulent Patent Prosecution

a. Celgene Failed to Disclose Material Information on Patentability of the Drug Composition Patents

240. The original, core patent for the composition of Celgene's thalidomide-derived drugs is the '517 patent, filed in 1996. Thalidomide, the drug on which Revlimid is based, was first on the market in 1957. The innovations on which the '517 patent is based are obvious in light of the innovations and research conducted long before Celgene began its effort to bring Thalomid and Revlimid to market; thus, the '517 patent and the subsequent patents derived from it are invalid.

241. Thalidomide was found to be immunotherapeutic in the 1960's, meaning it was known that thalidomide could treat diseases by inducing, enhancing or suppressing an immune response. Extensive scientific literature establishes the immunomodulatory properties of thalidomide and its derivative, lenalidomide, the active ingredient in Revlimid. It was well established that thalidomide has immunomodulatory properties, that thalidomide derivatives have the same immunomodulatory properties as thalidomide, that thalidomide was effective in the treatment of autoimmune diseases, that thalidomide derivatives inhibited Tumor Necrosis Factor Alpha, and that thalidomide is an angiogenesis inhibitor which also aids in the treatment of multiple

myeloma. There has been nothing unexpected or unanticipated about the effects or uses of Thalomid or Revlimid over the precedent scientific literature. In filing the '517 patent with the USPTO, none of these precedents were cited by Celgene. The USPTO examiners were not aware of key prior art when the '517 patent was granted.

242. In 2003, Celgene filed the '012 patent for thalidomide, a drug that had first been used almost half a century prior. Again, none of the relevant precedent above was cited in the USPTO filing by Celgene. Under 37 CFR 1.56, Celgene had a duty to disclose information material to patentability. Patents will be revoked and applications will be denied if this duty of disclosure was violated through bad faith or intentional misconduct. For the drug composition patents, as well as the distribution patents discussed below, Celgene has shown a pattern of omitting important precedents in USPTO filings for Thalomid and Revlimid.

b. Celgene Tried to Extend its Monopoly by Filing Redundant Drug Composition Patents Based on Previously Ill-Gotten Patents

243. In an effort to extend its monopoly on the sale of thalidomide derivatives, Celgene began filing additional patents on the polymorphic forms of lenalidomide. Polymorphs, also known as solvates or crystalline forms, of previously patented compounds are routinely developed as a standard practice in the pharmaceutical industry, according to a US patent examiner in a rejection of one of Celgene's polymorph patent applications, and generally not separately patentable.

244. However, Celgene managed to get the Polymorphs patents approved by the USPTO and filed in the FDA Orange Book, the '800 patent and the '217 patent,

which expire in 2027 and 2024 respectively. Since these patents have the latest expiration dates of any patents associated with Thalomid or Revlimid, they have been key patents cited in repeated attempts by Celgene to block generic competitors from the market. Celgene routinely cites these Polymorph patents against generic manufacturers that have filed generic Thalomid and/or Revlimid ANDAs.

245. In doing so, Celgene has also repeatedly left open the Polymorph patents to charges of invalidity and has repeatedly settled instead of testing the strength of these patents in court for fear of the result. When Natco Pharma Limited ("Natco Pharma") filed an ANDA for its generic version of lenalidomide, Celgene brought suit against it, Watson, and Arrow International Ltd., ("Arrow") (collectively, "Natco") claiming infringement.[69] The parties agreed to a Markman hearing to settle the meaning of disputed terms in the patent. Citing Celgene's own clarified definition of the term "hemihydrate," Natco amended its invalidity contentions to the '800 patent, arguing that it was invalid for indefiniteness, lack of enablement and lack of written description. When Celgene was unable to prevent Natco from raising these amended invalidity contentions, Celgene quickly settled with Natco, allowing Natco market share prior to the expiration of the patents rather than let its Polymorph patents face invalidation. Having learned a dangerous lesson, Celgene did what was necessary to

[69] *Celgene Corp. v. Natco Pharma Ltd*., No. 10-5197, 2015 WL 4138982 (D.N.J. Jul. 9, 2015). Celgene alleged that while Natco Pharma filed the ANDA, Arrow assisted Natco Pharma in preparing and filing the ANDA, and Watson prosecuted the ANDA before the FDA.

avoid a similar Markman hearing over the meaning of "crystalline" in its subsequent litigation against Dr. Reddy's.[70]

246. Celgene knew that the overbroad terms of its redundant Polymorph patents were an attempt to block generic competitors from bringing non-infringing products to market where the generic manufacturer has developed a suitable workaround to Celgene's patents. The claims of Celgene's other Polymorph patent, the '217 patent, also call out crystalline and hemihydrate forms, and are invalid for the same reasons as the '800 patent. Celgene has routinely used these Polymorph patents as part of its strategy to block generic competition through sham litigation, while agreeing to settle when the validity of these patents is called in to question.

247. The anticompetitive effect of Celgene's conduct with respect to the composition patents was to erect barriers to entry that significantly increased the costs of entry for would-be competitors, discouraged, and delayed generic entry.

c. Celgene Failed to Disclose Material Information on Patentability of The Distribution Method Patents

248. As discussed above, in 1998, Celgene only listed the '501 patent in the Orange Book in connection with Thalomid. Since then, it has listed numerous additional patents, including the '720, '976, '977, and '784 patents (together with the

[70] Letter to Court, *Celgene Corp. v. Dr. Reddy's Laboratories Ltd.*, 2:16-cv-7704 (D.N.J. Mar. 23, 2018), ECF No. 77. On the date that its responsive Markman pleadings were due, Celgene filed a letter informing the court that it resolved its claim construction disputes with Dr. Reddy's and would not be filing responsive pleadings.

'501 patent, the "Distribution Method Patents") in the Orange Book in connection with Thalomid.

249. The '501 and '720 patents were invalidated by the Patent Trial and Appeal Board ("PTAB") on October 26, 2016.[71]

250. The PTAB found the '501 patent invalid. In light of the combined disclosures of three (3) asserted prior art references as representative of the level of ordinary skill in the art, the PTAB found the claimed subject matter obvious.

251. Guidance regarding the clinical use and dispensing of thalidomide was provided by an existing publication in 1994 that identified a patient subpopulation of women who could and wished to become pregnant, warning that they should not be treated with Thalomid, and recommending counseling on the risks of thalidomide as well as the use of contraception.[72]

252. Further guidance was also provided by the existing pregnancy-prevention program for women users of Accutane, a Vitamin A analogue of isotretinoin and a known teratogenic drug. Accutane was subject to a program of preventative measures, such as pregnancy-risk warnings on packaging, targeting of women of childbearing age

[71] See *Coalition for Affordable Drugs VI LLC, et al., v. Celgene Corp.,* IPR2015-01092, Paper No. 73 (P.T.A.B. Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01092; IPR2015-01096, Paper No. 73 (P.T.A.B. Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01096; IPR2015-01102, Paper No. 75 (P.T.A.B. Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01102; IPR2015-01103, Paper No. 76 (Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01103 ("*Coalition*").

[72] R.J. Powell and J.M.M Gardner–Medwin, *Guideline for the clinical use and dispensing of thalidomide*, POSTGRAD MED. J. 79, 901–904 (1994) ("Powell").

for the pregnancy-prevention program, and communication between physicians and patients regarding the drug's teratogenic risk and the need to prevent pregnancy.[73]

253. Guidance for the use of a national database to register prescribers, pharmacies, and patients as a way to restrict access to drugs that could be potentially hazardous was also published well before the '501 patent was filed, such as the nation-wide registry for patients requiring clozapine, a potent anti-psychotic drug with potential for serious side effects.[74]

254. The PTAB found that a person of ordinary skill in the art would have understood how to implement Powell's teachings in clinical and pharmacy settings in view of the Accutane Pregnancy Prevention Program and the Clozaril (clozapine) controlled distribution model outlined in Dishman. The PTAB was not persuaded by Celgene's argument that the prior art did not specifically single out men who could impregnate a woman as a subgroup, noting that a skilled artisan would have recognized that the sperm of male patients could be damaged by teratogenic drugs and consequently result in birth defects if the male was to impregnate a female.[75]

255. The PTAB found the '720 patent invalid over the combined disclosures cited against the '501 patent for the original S.T.E.P.S. program, while finding that the

[73] Allen A. Mitchell et al., *A Pregnancy–Prevention Program in Women of Childbearing Age Receiving Isotretinoin*, NEW ENG. J. MED. 333:2, 101–06 (Jul. 13, 1995) ("Mitchell").

[74] Benjamin R. Dishman et al., *Pharmacists' role in clozapine therapy at a Veterans Affairs medical center*, AM. J. HOSP. PHARM. 51, 899–901 (Apr. 1, 1994) ("Dishman").

[75] *Coalition,* IPR2015–01092, Paper No. 73.

inherent dangers of Thalidomide would drive someone of ordinary skill in the art to proactively improve the system. Citing U.S. Patent No. 5,832,449 (issued Nov. 3, 1998, "Cunningham"), which describes an approval code used by prescribers and pharmacies to track and manage pharmaceutical products, the PTAB found that a person of ordinary skill in the art could predict that such an approval code could be utilized by prescribers and pharmacies to track and manage Thalomid and Revlimid. In light of this prior art, the PTAB invalidated the '720 patent as obvious.

256. As the PTAB noted, "[w]hen it benefitted [Celgene's] interests before the FDA, [Celgene] freely admitted that its 'plan [for thalidomide] is built on experience with restrictions on such other drugs with severe adverse effects as Accutane … and Clozaril."[76] Before the USPTO however, Celgene repeatedly failed to disclose the very materials that it relied on in presenting its program to the FDA, along with other similar prior art such as the Clozaril Patient Monitoring Service and numerous published works describing the features of REMS programs similar to Celgene's original and modified S.T.E.P.S. programs.

257. The '976 patent, the '977 patent, and the '784 patent, filed more than three years later, are nearly identical to the invalidated '501 and '720 patents. In fact, many of these patents were so similar that Celgene did not even bother changing the title or abstract describing the patent.

[76] IPR2015-01092, at 24 (P.T.A.B. Oct. 26, 2016).

258. Celgene also listed the '886 patent in the Orange Book in connection with Thalomid on November 20, 2012.

259. Celgene listed each of these patents in the Orange Book for both Thalomid, and later Revlimid, with full knowledge that protocols for the safe distribution of dangerous drugs like Thalomid and Revlimid have been in public use for years before Celgene filed any of its patent applications.

260. The Distribution Method Patents were obtained from the USPTO through knowing and willful fraud and are unenforceable. Celgene caused these patents to be listed in the Orange Book with knowledge that they were fraudulently obtained and are unenforceable. Celgene's withholding of material information on patentability with the intent to deceive the USPTO was done for the anticompetitive purpose of excluding generic competitors and maintaining a market monopoly.

261. The public prior use and/ or publication of Celgene's claimed "Distribution Method" inventions include:

i. The Clorazil Patient Monitoring Service ("CPMS")

262. The CPMS is a program for the distribution of Clorazil™. Clorazil is used to treat individuals with schizophrenia. A major side effect of Clorazil is agranulocytosis, a potentially fatal blood disorder.

263. Clorazil is distributed through the CPMS, which uses a national registry for patients, prescribers, and pharmacies. This registry identifies and reduces the risk of Clorazil- related complications.

264. The CPMS uses a computerized registry that includes patient information such as white blood cell counts to determine risk factors. The CPMS also tests white blood cell counts prior to starting Clorazil therapy. The CPMS mandates prescribing and dispensing only a limited supply of Clorazil after the prescriber determines that the risk is acceptable and provides the dispensing pharmacy with a report containing white blood cell counts and the doctor's opinion that the patient is eligible to receive required Clorazil. Additionally, the CPMS contains protocols for discontinuing treatment if the doctor determines, based on weekly blood tests, that the risk becomes unacceptable. Weekly refills are only provided after the same criteria for the initial dispensation are met again at the start of each week.

265. The CPMS qualifies as prior art to the claims of the Distribution Method Patents and the '886 patent under 35 U.S.C. § 102(b), because it was commercially used in the United States more than one (1) year before the earliest priority date of the Distribution Method Patents and the '886 patent.

266. The applicants of those patents, their agents, and/or their attorneys did not disclose the CPMS to the USPTO during pendency of the applications from which the Distribution Method Patents issued.

ii. Honigfeld, "Effects of the Clozapine National Registry System on Incidence of Deaths Related to Agranulocytosis," *Psychiatric Services*, 47(1):52-56 (1996) ("Honigfeld I")

267. Honigfeld I describes details of the CPMS and qualifies as prior art to the Distribution Method Patents and the '886 patent under 35 U.S.C. § 102(b), because it

was publicly available and accessible more than one (1) year prior to the earliest priority date of the Distribution Method Patents and the '886 patent.

268. The applicants, their agents, and/or their attorneys did not disclose the Honigfeld I to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

iii. Honigfeld, *et al*., "Reducing Clozapine-Related Morbidity and Mortality: 5 Years of Experience With the Clozaril National Registry," J. *Clin. Psychiatry* 59 (suppl 3): 3-7 (1998) ("Honigfeld II")

269. Honigfeld II also details the protocols of the CPMS and qualifies as prior art to the '501 and '976 patents under 35 U.S.C. § 102(a) because it was publicly available information prior to the earliest priority date of the '501 and '976 patents. Honigfeld II qualifies as prior art to the '720, '977, '784, and '886 patents under 35 U.S.C. § 102(b), because it was publicly available information more than one (1) year prior to the earliest priority date of the '720, '977, '784, and '886 patents.

270. The applicants, their agents, and/or their attorneys did not disclose Honigfeld II to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

iv. The "Guide to the Clozaril Patient Monitoring Service," Novartis Pharmaceuticals UK Ltd. (Nov. 1997) ("The Guide")

271. Details of the CPMS are described in the Guide, which qualifies as prior art to the '501 and '976 patents under 35 U.S.C. § 102(a) because it was publicly available prior to the earliest priority date of the '501 and '976 patents. The Guide

qualifies as prior art to the '720, '977, '784, and '886 patents under 35 U.S.C. §102(b), because it was publicly available more than one (1) year prior to the earliest priority date of the '720, '977, '784, and '886 patents.

272. The applicants, their agents, and/or their attorneys did not disclose the Guide to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

v. The ACCUTANE Pregnancy Prevention Program ("PPP")

273. The PPP is a program for the distribution of Accutane, known generically as isotretinoin. The PPP was developed and implemented to prevent fetal exposure to isotretinoin. The PPP included an information package for physicians warning of the risks of dispensing the drug to pregnant women, a patient informed consent form containing warnings detailing the risks associated with Accutane and the requirements to receive Accutane and required pregnancy testing and birth control counseling before the patient started a course of Accutane therapy. It also required a patient survey on compliance.

274. The PPP qualifies as prior art to the claims of the Distribution Method Patents and the '886 patent under 35 U.S.C. § 102(b), because it was commercially used in the United States more than one (1) year prior to the earliest priority date of the Distribution Method Patents and the '886 patent.

275. The applicants, their agents, and/or their attorneys did not disclose the PPP to the USPTO during the pendency of the applications from which the Distribution Method Patents and the '886 patent issued.

vi. The Accutane PPP Package, a 1994 patent and prescriber information package for Accutane, distributed by Roche Pharmaceuticals ("PPP Package")

276. The PPP Package described details of the PPP. It qualifies as prior art to the Distribution Method Patents and the '886 patent under 35 U.S.C. § 102(b), because it was publicly available more than one (1) year prior to the earliest priority date of the Distribution Method Parents and the '886 patent.

277. The applicants, their agents, and/or their attorneys did not disclose the PPP Package to the USPTO during the pendency of the applications from which the Distribution Method Patents and the '886 patent issued.

vii. A Centers for Disease Control public meeting entitled "Preventing Birth Defects Due to Thalidomide Exposure" and transcript from March 26, 1997 ("The CDC Meeting and Transcript")

278. On March 26, 1997, the CDC held a public meeting to discuss thalidomide and its associated risks. The meeting was attended by at least two Celgene employees: Dr. Jerome Zeldis, the then Vice President of Medical Affairs at Celgene, and Mr. Bruce A. Williams, a named inventor for the Distribution Method Patents and the '886 patent.

279. The transcript of the CDC Meeting shows that the PPP and the CPMS were discussed, as was the use of the protocols in those two systems in designing a similar protocol for thalidomide.

280. The CDC Meeting attendees discussed potential elements to be part of a thalidomide distribution program, including: (1) patient, pharmacy, and prescriber registration; (2) counseling patients about the risks of thalidomide and the need for contraception; (3) required pregnancy testing before thalidomide is prescribed; (4) monthly testing thereafter; (5) providing proof that the patient is not pregnant before the drug can be dispensed and providing contraceptives with the drug; (6) limiting the length of the prescription to a monthly supply; and (7) requiring return to the prescriber before refilling the prescription.

281. The CDC Transcript was publicly available under the Freedom of Information Act more than one (1) year prior to the earliest priority date of the Distribution Method Patents and the '886 patent. It therefore qualifies as prior art to the Distribution Method Patents and the '886 patent under 35 U.S.C § 102(b).

282. The applicants, their agents, and/or their attorneys did not disclose the CDC Meeting or the CDC Transcript to the USPTO during the pendency of the applications from which the Distribution Method Patents and the '886 patent issued.

viii. Zeldis, *et al*., "S.T.E.P.S.™: A Comprehensive Program for Controlling and Monitoring Access to Thalidomide," *Clinical Therapeutics* 21(2): 319-30 (1999) ("Zeldis")

283. Zeldis qualifies as prior art to the '720, '977, and '784 patents under 35 U.S.C. § 102(b), because it was publicly available more than one (1) year prior to the earliest priority date of the '720, '977, and '784 patents.

284. Zeldis is co-authored by Celgene employees, including Zeldis and named inventor Williams. It described the S.T.E.P.S. program developed by Celgene, with the guidance of the FDA, to monitor and control access to thalidomide. Zeldis states that the S.T.E.P.S. protocol is "based in part on experience gained with other drugs—specifically isotretinoin and clozapine— that offer important clinical benefits but carry the potential for serious harm."

285. Zeldis states:

> Celgene has incorporated elements of both these successful programs into the S.T.E.P.S.™ program for controlling the distribution of thalidomide. Educational materials for patients and physicians and label warnings similar to those used in the isotretinoin program are coupled with clinician and patient registration and testing similar to those used in the clozapine program.

286. Zeldis cites Honigfeld I and Honigfeld II in its discussion of Clorazil.

287. The applicants, their agents, and/or their attorneys did not disclose Zeldis to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

ix. The September 4 and 5, 1997 Center for Drug Evaluation and Research of the Food and Drug Administration public meeting ("The CDER Meeting and Transcript")

288. The CDER Meeting was recorded in a publicly-available transcript and at least seven (7) Celgene employees, including named inventor Bruce Williams who made a presentation on preventing fetal exposure to thalidomide, attended the meeting.

289. Williams stated:

> [w]e recognize that there may be some models in the marketplace today which could serve as at least a starting point in our thinking as we develop this program. Two of them came to mind that I would like to just speak very briefly to, to indicate why we feel that they are relevant models, but also where we feel they may not go far enough for this particular circumstance. The first is one that this committee, particularly, is very familiar with. And that is Roche's Accutane, used to treat severe acne, and known to be a human teratogen.

290. Williams described the Accutane system, the PPP, and its purported drawbacks, which he described as a lack of a mandatory registry and an inability for a pharmacist to determine at dispensing whether the patient has participated in Roche's program.

291. He noted that the PPP's purported drawbacks drove Celgene to analyze the CPMS protocol, to which he stated:

> In looking at how Sandoz structured this [Clozaril] system, we began to see that by taking elements from the Roche program [Accutane], elements from the Clozaril program and other unique elements, we would create a system that really would be state of the art, represent a significant step, we believe, forward in the ability to make drugs like thalidomide available to patients who need it, while at the same time providing a very high margin for protection.

292. The CDER Transcript qualifies as prior art to the Distribution Method Patents and the '886 patent under 35 U.S.C. § 102(a), because it was publicly available under the Freedom of Information Act prior to the earliest priority date of the Distribution Method Patents and the '886 patent. The CDER Transcript also qualifies as prior art to the '720, '977, and '784 patents under 35 U.S.C. § 102(b), because it was publicly available information under the Freedom of Information Act more than one (1) year prior to the earliest priority date of the '720, '977, and '784 patents.

293. The applicants, their agents, and/or their attorneys did not disclose the CDER Transcript to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

x. The September 9 and 10, 1997 public workshop held by the National Institutes of Health, FDA, and CDC, entitled "Thalidomide: Potential Benefits and Risks, Open Public Scientific Workshop" ("The NIH Meeting and Transcript")

294. The NIH Meeting on September 10, 1997 was recorded in a publicly available transcript. There, named inventor Williams gave a presentation regarding a Celgene proposal "for a distribution and education system" for thalidomide.

295. Williams stated:

> when we started in this endeavor we looked to see what else was in the marketplace that might serve as a model. We accepted that we were unlikely to find any single model that carried all of the elements that would likely be necessary for this drug, but we did find two that in part covered many of the elements that might be required. Accutane, we heard about yesterday. Comprehensive educational program, counseling, and good contraception, informed consent, a package with integrated product warnings, and a surveillance system, albeit voluntary. Many elements that clearly with either

> change or updating or enhancement would likely be relevant to what needed to be done for thalidomide. We also heard about the Novartis program for Clozaril, a drug used to treat schizophrenia and introduced in an era where existing antischizophrenia drugs were not particularly effective for many patients. In addition, they carried their own baggage of side effects. However, in a small proportion of patients who take this drug, a granular cytosis [sic] can develop in a very short period of time.

296. The NIH Transcript qualifies as prior art to the Distribution Method Patents and the '886 patent under 35 U.S.C. § 102(a), because it was publicly available under the Freedom of Information Act before the earliest priority date of the Distribution Method Patents and the '886 patent. The NIH Transcript also qualifies as prior art to the '720, '977, and '784 patents under 35 U.S.C. § 102(b), because it was publicly available and accessible under the Freedom of Information Act more than one (1) year prior to the earliest priority date of the '720, '977, and '784 patents.

297. The applicants, their agents, and/or their attorneys did not disclose the NIH Meeting or Williams' presentation at the NIH Meeting to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

298. Each of the above enumerated publications, meetings, or programs constitutes prior art that Celgene was required to disclose but failed to disclose to the USPTO, for each of the Distribution Method Patents.

299. In its 2010 application for the '886 patent, Celgene failed to disclose the existence of the PPP Package or the CDC Transcript. Had Celgene disclosed the PPP Package or the CDC Transcript, the USPTO would not have issued Celgene the '886 patent.

xi. The Distribution Method Patents are Unenforceable

300. All the above prior arts are material to the patentability of the Distribution Method Patents. They firmly establish, *prima facie*, unpatentability under 35 U.S.C. §§ 102 and 103. Each prior art listed is material to the patentability of the Distribution Method Patents because, but for Celgene's failure to disclose them, the USPTO would not have allowed any or all of the claims of the Distribution Method Patents to issue.

301. All the above prior arts are material to the patentability of the Distribution Method Patents because, individually and/or taken together, they contradict or are inconsistent with positions the applicants took in opposing arguments of unpatentability relied on by the USPTO or asserting arguments of patentability.

302. All of the above prior arts are material to the patentability of the Distribution Method Patents because, individually and/or taken together, they constitute information that a reasonable Examiner reviewing the applications would consider material in determining whether to allow the proposed claims to issue.

303. The applicants of the Distribution Method Patents, their agents, and/or their attorneys and anyone else substantively involved in the application, owed a duty of good faith and candor to the USPTO during the pendency of the applications from which the Distribution Method Patents issued. Pursuant to that duty, they were required to disclose all information material to the applications from which the Distribution Method Patents issued.

304. During the pendency of the applications from which the Distribution Method Patents issued, the applicants, their agents, attorneys, and anyone else substantively involved in the prosecution were aware of the above prior arts.

305. While the applications from which the Distribution Method Patents issued were pending, the applicants, their agents, attorneys, and anyone else substantively involved in the prosecution knew that the above listed prior arts were material to those applications.

306. The Distribution Method Patents applicants, their agents, attorneys, and anyone else substantively involved in the prosecution withheld the above listed prior arts with the intent to deceive the Patent Examiner.

307. The Distribution Method Patents applicants, their agents, attorneys, and anyone else substantively involved in the prosecution knowingly and willfully misrepresented and omitted material information during the pendency of the applications from which the Distribution Method Patents issued. But for these misrepresentations and omissions, the Distribution Method Patents would not have issued.

308. The Distribution Method Patents were obtained from the USPTO through knowing and willful fraud; accordingly, they are unenforceable.

309. The Supreme Court's decision in *Alice Corp. v. CLS Bank International*,[77] after the distribution method patents were issued, has raised doubts that REMS patents

[77] Alice Corp. Pty. Ltd. v. CLS Bank International, et al., 573 U.S. 208 (2014).

are even patentable subject matter at all. In its decision, the Court created a new test for patents that are directed to abstract ideas, such as a strategy for distribution, in which the court will examine the elements of the claim to determine whether it contains an 'inventive concept' that is enough to 'transform' the abstract idea in the claims enough to make it eligible for patent protection. Simply performing a process that has been done before, such as safely dispersing prescriptions, and performing it on a computer does not transform an abstract idea into patentable subject matter. Since *Alice,* patents for REMS distribution methods have been invalidated as unpatentable abstract ideas.[78]

310. Celgene caused the Distribution Method Patents to be listed in the Orange Book with knowledge that they were fraudulently obtained from the USPTO and are unenforceable. Celgene listed the Distribution Method Patents in the Orange Book with the intent and purpose of impeding thalidomide and lenalidomide ANDA filings and delaying FDA approval of any ANDA's for at least thirty (30) months pursuant to 21 U.S.C. § 355 (j)(5)(B)(iii).

xii. Celgene Tried to Extend Its Monopoly by Filing Redundant Distribution Method Patents Based on its Previously Ill-Gotten Patents

311. Celgene applied for another patent, the '886 Patent, on December 13, 2010, just after Barr and Natco each filed an ANDA for thalidomide. Celgene's patent application did not disclose the PPP Package or the CDC Transcript as prior art.

[78] *See Par Pharmaceutical, Inc., et al., v. Jazz Pharmaceuticals, Inc.,* IPR2015-00554, Paper No. 68 (P.T.A.B. July 27, 2016) for patent 7,668,730 previously held by Jazz Pharmaceuticals, https://portal.unifiedpatents.com/ptab/case/IPR2015-00554.

312. Both the PPP Package and the CDC Transcript are material to the patentability of the '886 patent. These two (2) prior arts contradict or are inconsistent with positions the applicants took in opposing arguments of unpatentability relied on by the USPTO or asserting arguments of patentability. They are also material because they constitute information that a reasonable Examiner would consider important in deciding whether to allow the proposed claims of the '886 patent to issue. Had the USPTO been aware of those undisclosed prior art references, the USPTO would not have allowed any or all of the claims of the '886 patent to issue.

313. Celgene obtained the '886 patent on November 20, 2012, through knowing and willful fraud. It is therefore unenforceable. Celgene further caused the '886 patent to be listed in the Orange Book with knowledge that it was fraudulently obtained from the USPTO and is unenforceable. Celgene acted with the intent to thwart or otherwise discourage generic manufacturers from filing thalidomide and/or lenalidomide ANDAs, and to delay FDA approval of any such ANDA for at least thirty (30) months pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

314. The applicants of the '886 patent, their agents, attorneys, and anyone else substantively involved in the prosecution owed a duty of good faith and candor to the USPTO during the pendency of the applications from which the '886 patent issued. As part of that duty of candor, they were required to disclose information material to the application from which the '886 patent issued.

315. During the pendency of the application from which the '886 patent issued, the applicants, their agents, attorneys, and anyone else substantively involved in the

prosecution were aware of the PPP Package and the CDC Transcript, knew that that these two (2) prior arts were material to that application and withheld them with the intent to deceive the Patent Examiner. But for these omissions and misstatements, the '886 patent would not have issued.

d. Celgene Attempted to Extend Its Monopoly by Filing Redundant Dosing Patents and Failed to Disclose Material Information on Patentability of the '745 Patent

316. Celgene filed the '745 patent for methods and compositions for inhibition of angiogenesis in 2006, listing Robert D'Amato as inventor. D'Amato had filed and was granted the 5,593, 990 (the "'990 patent") patent for methods and compositions for inhibition of angiogenesis in 1995, along with several other patents relating to thalidomide analogs, based on his research with The Children's Medical Center Corporation ("CMCC") in Boston. Around this same time, Celgene was beginning to file its initial patents for thalidomide analogs, which resulted in Celgene and the company to whom CMCC had licensed its patents, EntreMed, suing each other for infringement and challenging the validity of the other's patents.[79] This dispute was resolved in 2002 when the parties entered into an exclusive license agreement allowing Celgene a worldwide, exclusive license in CMCC's entire portfolio of thalidomide analog patents in exchange for paying royalties.

317. When Celgene filed for the '745 patent, it did not cite the '990 patent or any of the other D'Amato dosing patents that they held the exclusive license for that

[79] *Children's Med. Center Corp. v. Celgene Corp*., No. 13-11573, 2016 WL 3561603 (D. Mass. Feb. 23, 2016).

dealt with treating disease states resulting from angiogenesis. The addition that anti-inflammatory drugs and NSAIDS can inhibit angiogenesis alone or in combination with thalidomide and its analogs was already disclosed by prior art. Celgene filed this redundant patent in an attempt not only to extend its monopoly but to do so in a way to not have to continue to pay royalties to CMCC. Though its attempts to maintain patent protection without paying the accompanying royalties were unsuccessful,[80] Celgene was able to leverage the unenforceable and invalid '745 patent in its sham litigation with Lannett, discussed below.

2. Celgene Filed Sham Litigations to Prevent or Delay Generic Entry

318. In 2008, Celgene filed a patent infringement lawsuit against Barr, and in 2015 against Lannett, for their thalidomide ANDAs.

319. In 2010, Celgene filed a patent lawsuit against Natco for its lenalidomide ANDA. In 2016, Celgene filed a patent lawsuit against Dr. Reddy's for its lenalidomide ANDA. In 2017, Celgene filed patent lawsuits against Zydus Pharmaceuticals ("Zydus") and against CIPLA Ltd. ("CIPLA") for their lenalidomide ANDAs. In 2018, Celgene filed patent lawsuits against Lotus Pharmaceuticals ("Lotus") and Sun Pharmaceutical ("Sun") for their lenalidomide ANDAs.

320. In all cases, Celgene complained that the generic versions of Thalomid and Revlimid infringed Celgene's patents related to its REMS procedures of ensuring safe

[80] *Children's Med. Center Corp. v. Celgene Corp*., No. 13-11573, 2016 WL 5746358 (D. Mass. Sept. 30, 2016).

use of the drug. Barr, Natco, Lannett, and Dr. Reddy's each counterclaimed, alleging that Celgene's patents are invalid as prior art or for obviousness, under 35 U.S.C. §§ 102 and/or 103. Because Celgene knew that its patents were invalid, it also must have known that the litigation to enforce the invalid patents would be unsuccessful. It brought the actions only because the filing would delay generic entry into the markets.

a. Celgene's Sham Litigation and Citizen Petition Against Barr

321. Barr filed an ANDA with the FDA for a generic version of Thalomid in September 2006. In its application, Barr alleged that Celgene's patents were invalid.

322. As a result, Celgene filed a lawsuit against Barr in 2007,[81] and a citizen petition on September 20, 2007, one (1) year after Barr filed its ANDA with the FDA. The lawsuit was filed solely to take advantage of the 30-month statutory stay of FDA approval for Barr's generic thalidomide product. The patents at issue concerned the method-of-use rather than the pharmaceutical process; the patents were the result of academic conferences, and thus prone to invalidity on the grounds of obviousness. The litigation was a means to collusively and illegally ensure Celgene's continued monopoly.

323. In the lawsuit, Barr counterclaimed, alleging monopolization, conspiracy to monopolize, and anticompetitive acts, including sham litigation.

[81] *Celgene Corp. v. Barr Laboratories, Inc., et al.,* No. 2:07-cv-286 (D.N.J. Jan. 18, 2007) (J. Wigenton).

324. Upon information and belief, while that action was pending, Barr predicted that its generic version of Thalomid, thalidomide capsules in 50mg, 100mg, 150mg, and 200mg, would launch on the market on June 8, 2009. At the same time, it predicted filing an ANDA for its generic version of Revlimid, lenalidomide capsules, on December 27, 2009, and launching that product August 27, 2012.

325. In addition to filing sham litigation against Barr, on September 20, 2007, Celgene also filed a baseless citizen petition with the FDA urging it not to approve Barr's thalidomide ANDA. At a meeting with Celgene in 2012, FDA's Jane Axelrad, Associate Director for Policy at CDER, commented "since 2007, Celgene's citizen's petition states there are safety concerns and this is because the company does not want generics on the market."[82] In its citizen petition, Celgene requested that the FDA withhold approval of any generic thalidomide product, or alternatively: i) require the application for generic thalidomide to be subject to the same conditions of approval applied to Thalomid under Subpart H of 21 C.F.R. Part 314; and ii) prohibit the restricted distribution program for the generic thalidomide product from authorizing prescriptions for, and registering patients with, multiple myeloma, in violation of Celgene's orphan drug exclusivity, which would expire in 2013.

326. Celgene's petition was meritless. It lacked any reasonable regulatory, scientific, medical, or other basis. The FDA lacked statutory authority to withhold approval of generic thalidomide on the bases given by Celgene or to require the actions

[82] Exhibit to MSJ Opp., Dkt. No. 285-15.

Celgene requested. Like its litigation against Barr, this citizens petition was also a sham designed to maintain Celgene's monopoly.

327. On December 19, 2008, Barr responded to the petition, arguing that it "is nothing more than yet another attempt by a brand company to block all generic competition using market exclusivity protecting just a single approved indication."[83] Barr explained that Celgene's pretextual safety concerns were "hyperbole designed to improperly play on the public's fears regarding thalidomide," and that Barr's proposed thalidomide would be safe and its label would contain all precautionary information contained in the Thalomid label. Specifically, Barr argued that the law permits it to carve-out from its label Thalomid's protected MM indication, and that "Barr's Thalidomide Labeling Need Not Contain The Multiple Myeloma Indication To Ensure The Safe And Effective Use Of The ANDA Product."

328. Nearly six (6) years later on September 30, 2014, FDA denied Celgene's citizen petition. Specifically, FDA "den[ies] your request that FDA decline to approve any ANDA for thalidomide."

329. Celgene's patent lawsuit against Barr initiated a 30-month stay of FDA approval for Barr's thalidomide ANDA pursuant to 21 U.S.C. § 355 (j)(5)(B)(iii).

330. The parties engaged in discovery through spring 2010. On May 5, 2010, as part of a settlement agreement, the terms of which are confidential, Barr/Teva[84]

[83] Exhibit to MSJ Opp., Dkt. No. 285-17.

[84] Teva purchased Barr in 2008.

requested the FDA withdraw Barr's thalidomide ANDA. Barr/Teva withdrew its ANDA due to "lack of commercial viability" while maintaining that "we still believe Teva or another drug maker may file a paragraph IV filing for Revlimid at some point despite the potential difficulties challenging a controlled-distribution program."[85] On May 26, 2010, the Court approved Barr and Celgene's stipulation of dismissal. This settlement had the anticompetitive effect of keeping Barr's generic thalidomide and generic lenalidomide off the market.

331. The settlement's terms may have included a reverse payment agreement from Celgene to Barr. A reverse payment patent settlement exists when a patent holder, here Celgene, settles a patent infringement action that the patent holder brought by making a payment to a potential competitor in consideration for their agreement to either delay or refrain from entering the patent holder's market.

332. This type of illegal and anticompetitive settlement artificially blocks competition, allowing Celgene to continue charging higher prices. When a patent holder can control an entire market through sham litigation, they can install supracompetitive prices for necessary products, leaving consumers with no choice but to pay the artificially inflated prices.

333. A reverse payment not only allows a patent holder to stranglehold a market, but it also indicates the invalidity of Celgene's patents. Celgene's patents at issue concern method-of-use for Thalomid and Revlimid, rather than the

[85] Exhibit to MSJ Opp., Dkt. No. 285-17.

pharmaceutical process itself. Moreover, Celgene's patents were largely based on academic and government studies and conferences and are thus prone to invalidity on the grounds of obviousness. Celgene's patent litigation was not in good faith.

334. But for the confidential settlement which may have contained illegal pay-for- delay provisions, Barr would have pursued its 2008 thalidomide ANDA, filed a generic lenalidomide ANDA, and launched both of those products. Celgene's conduct therefore had the anticompetitive effect of delaying and indefinitely postponing the testing and introduction of generic alternatives.

b. Celgene's Sham Litigation Against Lannett

335. In late 2013 Lannett announced that its BE studies were going well and it expected to submit a thalidomide ANDA application to the FDA in January 2014. In December 2014, Lannett filed ANDA No. 206-601 with the FDA to gain approval to market its generic version of Thalomid. Lannett also filed a Paragraph IV certification, alleging that Celgene's patents were invalid.

336. Celgene filed a patent lawsuit against Lannett in response on January 30, 2015 alleging infringement of fifteen (15) different patents.[86] Lannett filed counterclaims against Celgene, alleging monopolization, conspiracy to monopolize, and anticompetitive acts, including sham litigation.

[86] *Celgene Corp. v. Lannett Holdings, Inc.*, No. 2:15-cv-00697 (D.N.J. Jan. 30, 2015) (Wigenton, J.).

337. Celgene's lawsuit triggered a 30-month statutory stay of FDA approval of Lannett's generic thalidomide product.[87]

338. On October 10, 2017, Celgene and Lannett stipulated to a settlement wherein Lannett would change its Paragraph IV certification on the '745 patent to a Paragraph III certification and no longer seek FDA approval of its ANDA prior to the expiration of the '745 patent and Celgene would dismiss its claims of patent infringement.

339. On October 30, 2017, Lannett and Celgene announced that they entered into a settlement and license agreement related to Thalomid, that would permit Lannett to manufacture and market its generic thalidomide product as of August 1, 2019. The terms of the license agreement are confidential.

340. The anticompetitive effect of Celgene's conduct was to delay Lannett's initial ANDA filing, and then to further delay FDA approval of Lannett's generic thalidomide product, and finally, to delay the entry date of Lannett's thalidomide product.

c. Celgene's Sham Litigation Against Natco, Arrow, and Watson

341. Natco Pharma is an Indian generic prescription drug manufacturer that partnered with Arrow and Watson to produce and market a generic version of Revlimid.

[87] *See* 21 U.S.C. § 355(j)(5)(B)(iii).

342. On or about August 30, 2010, Natco sent Celgene a required notice letter of its Paragraph IV certifications, which contained a detailed factual and legal statement as to why Celgene's Distribution Method Patents, and certain patents that Celgene listed in the Orange Book in connection with NDA No. 21-880, that related to the chemical composition of Revlimid, including, the '517 patent, 6,281,230 patent ("'230 patent"), 6,555,554 patent ("'554 patent"), 7,119,106 patent ("'106 patent"), and the '800 patent, among others, were invalid, unenforceable, and /or not infringed by Natco's lenalidomide ANDA.

343. On approximately September 24, 2010, Natco filed ANDA No. 201-452 seeking approval for 5 mg, 10 mg, 15mg and 20mg lenalidomide capsules. The ANDA showed that Natco's generic lenalidomide products are bioequivalent to Celgene's Revlimid.

344. Celgene filed a patent infringement suit against Natco on October 8, 2010. In November and December 2012, Celgene caused additional patents related to the chemical composition of Revlimid, patent number 8,288,415 ("'415 patent") and the '886 patent, respectively, to be listed in the Orange Book in connection with Revlimid.

345. On November 18, 2010, Natco filed its Answer and counterclaimed that its ANDA did not infringe Celgene's relevant patents, and that Celgene's relevant patents were invalid and unenforceable.

346. On March 14, 2013, Natco sent Celgene another required notice letter of its Paragraph IV certifications, which contained a detailed factual and legal statement

explaining that the '415 and '886 patents are invalid, unenforceable, and/or not infringed by Natco's lenalidomide generics.

347. On April 10, 2013, Celgene caused the 8,404,717 ("'717 patent") to be listed in the Orange Book in connection with Revlimid. On April 30, 2013, the USPTO issued patent 8,431,598 ("'598 patent") to Celgene.

348. On May 6, 2013, Celgene filed its Fifth Amended Complaint against Natco Pharma, Arrow and Watson, claiming that Natco's lenalidomide generics would infringe the Distribution Method Patents, the '886 patent, and the '517, '230, '554, '106, '800, '415, '717, and '598 patents. The invalidity of these patents is discussed above.

349. Natco argued that the '517, '230, '554, '106, '800, '415, '717, and '589 patents were invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112 and/or doctrines of double patenting. Moreover, Natco argued that its lenalidomide generics did not infringe Celgene's '800 patent as Natco's lenalidomide did not contain lenalidomide hemihydrate.

350. Celgene argued, and the Court agreed, that "hemihydrate" means "a hydrate containing approximately half a mole of water to one mole of the compound forming the hydrate."

351. Accordingly, using this definition, Celgene's '800 patent is invalid under 35 U.S.C. § 112 for indefiniteness and lack of written description and lack of enablement.

352. Natco filed counterclaims against Celgene, alleging fraud on the USPTO, and invalid and/or unenforceable patents. Celgene's sole purpose in litigating the alleged infringement was to delay generic entry into the Revlimid market.

353. On December 22, 2015, Celgene announced that it reached a settlement with Natco. On January 4, 2016, the District Court issued a consent judgment dismissing all claims with prejudice. Under the terms of the settlement agreement, Natco Pharma, Arrow, and Watson are enjoined from marketing unlimited quantities of generic lenalidomide until January 1, 2026, one (1) year before the expiration of the at issue patents. Starting in March 2022, Natco will be allowed to market a limited amount of generic lenalidomide. The allowed quantity will increase each year until 2026. The volume limit is not "expected to exceed one-third of the total lenalidomide capsules dispensed in the U.S. in the final year of the volume-limited license."

354. The anticompetitive effect of Celgene's conduct was to delay Natco's ANDA and generic entry in the Revlimid market and artificially limit Natco's ability to take market share from Celgene through lower prices. Though Natco filed its lenalidomide ANDA in September 2010, it cannot bring its generic to market until 2022 at limited volumes. Consequently, a generic lenalidomide product continues to be unavailable and UHS is forced to pay for brand-name Revlimid at Celgene's supracompetitive prices until at least 2022, and given volume limitations, likely until at least 2026 (and potentially longer).

d. Celgene's Sham Litigation Against Dr. Reddy's

355. On October 20, 2016, Celgene filed yet another patent infringement action, this time against Dr. Reddy's, for filing its ANDA for various dosages of its generic alternative to Revlimid, allegedly infringing Celgene's '800 patent, 7,855,217 patent ("'217 patent"), 7,968,569 patent ("'569 patent"), 8,530,498 patent ("'498 patent"), 8,648,095 patent ("'095 patent"), 9,101,621 patent ("'621 patent"), and the 9,101,622 patent ("'622 patent").[88]

356. In its answer, filed on November 18, 2016, Dr. Reddy's claimed that all seven (7) patents asserted were not duly and/or lawfully issued. It also counterclaimed that all seven (7) patents were invalid and/or unenforceable. The parties filed opening Markman briefs on December 2017. On March 23, 2018, Celgene notified the court that the parties resolved their claim construction disputes and would not be filing responsive Markman briefs.

357. A settlement conference was held on January 10, 2019. The anticompetitive effect of Celgene's conduct is to again delay and prevent generic entry into the lenalidomide market.

e. Celgene's Sham Litigation Against Zydus

358. On April 12, 2017, Celgene filed a patent infringement action against Zydus and their healthcare arm, Cadila Healthcare Limited, for filing ANDA No. 210154 for various dosages of its generic alternative to Revlimid, allegedly infringing

[88] Celgene Corp. v. Dr. Reddy's Laboratories, Inc., No. 2:16-cv-7704 (D.N.J.).

Celgene's same '800 patent, '217 patent, '569 patent, '498 patent, '095 patent, '621 patent, and the '622 patent.[89] This combination of patents have become central to Celgene's strategy of blocking generic competitors.

359. On August 7, 2017, Zydus filed its answer and counterclaimed that each of Celgene's asserted patents are invalid, unenforceable, or noninfringed.

360. That case is ongoing.

361. The anticompetitive effect of Celgene's conduct, including filing yet another sham litigation, is to delay and prevent generic entry into the lenalidomide market.

f. Celgene's Sham Litigation Against Cipla

362. On August 15, 2017, Celgene filed a patent infringement action, this time against CIPLA, for filing its ANDA No. 210435 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe the same combination of the '800 patent, '217 patent, '569 patent, '498 patent, '095 patent, '621 patent, and the '622 patent.[90]

363. On August 16, 2018, Celgene stipulated to a dismissal of its claims regarding the '217 patent and filed a covenant not to sue CIPLA for infringement of the '217 patent.

364. That case is ongoing.

---

[89] *Celgene Corp. v. Zydus Pharmaceuticals (USA) Inc. et al*., No. 2:17-cv-2528 (D.N.J. Apr. 12, 2017).

[90] *Celgene Corp. v. CIPLA Ltd*., No. 2:17-cv-6163 (D.N.J. Aug. 15, 2017).

365. The anticompetitive effect of Celgene's conduct, including filing yet another sham litigation, is to delay and prevent generic entry into the lenalidomide market.

g. Celgene's Sham Litigation Against Alvogen and Lotus

366. On July 10, 2018, Celgene filed a patent infringement action against Lotus and Alvogen, Inc. ("Alvogen") for filing ANDA No. 210480 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe their 7,977,357 patent (the "'357 patent"), 8,193,219 patent (the "'219" patent), and the 8,431,598 patent (the "'598" patent).[91] The patents that Celgene has claimed would be infringed in this case, however, have not been submitted to the Orange Book by Celgene in association with Revlimid as required pursuant to 21 U.S.C. §355(b)(1) and attendant FDA regulations. Celgene was required to list with their NDA, or within thirty days for a new patent after the NDA has been submitted, any patents for which an infringement claim could reasonably be asserted against an unlicensed entity attempting to manufacture, use or sell their drug. By citing these patents that were not filed in the Orange Book, Celgene is either filing a frivolous infringement claim for a patent that it does not believe could be reasonably asserted or failing to list patents properly which could give rise to administrative action or potentially additional antitrust liability if done in an attempt to delay filing and further extend their monopoly.

[91] *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al*, No. 2:18-cv-11518-SDW-LDW (D.N.J. July 10, 2018).

367. In their notice letter to Celgene, Lotus and Alvogen also alleged that the '517 patent, the '720 patent, the '977 patent, the '784 patent, the '740 patent, the '800 patent, the '217 patent, the '569 patent, the '886 patent, the '717 patent, the '498 patent, the '531 patent, the '095 patent, the '120 patent, the '621 patent, and the '622 patent were all invalid, unenforceable, or would not be infringed by activity described in Lotus and Alvogen's Paragraph IV Certification.

368. That case is ongoing.

369. The anticompetitive effect of Celgene's conduct, including filing yet another sham litigation, is to delay and prevent generic entry into the lenalidomide market.

h. Celgene's Sham Litigation Against Sun

370. In Spring 2018, Sun filed its ANDA for generic lenalidomide. On May 30, 2018, Sun sent written notice of its Paragraph IV Certification to Celgene alleging that the patents-in- suit were invalid and/or would not be infringed by Sun's ANDA.

371. On July 13, 2018, Celgene filed yet another patent infringement action against a generic manufacturer, this time against Sun Pharmaceuticals for filing ANDA No. 211846 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe their '800 patent, '217 patent, and their '569 patent.[92]

372. On August 14, 2018, Sun filed its answer and counterclaim, alleging that Celgene's asserted patents were invalid, unenforceable, or uninfringed.

[92] *Celgene Corp. v. Sun Pharmaceutical Industries, Inc. et al*., No. 2:18-cv-11630 (D.N.J. July 13, 2018).

373. That case is ongoing.

374. The anticompetitive effect of Celgene's conduct, including filing yet another sham litigation, is to delay and prevent generic entry into the lenalidomide market.

D. Celgene Used Unlawful Kickbacks and Off-Label Promotions to Increase Its Supracompetitive Profits

375. During the relevant time period, Celgene marketed Thalomid for the treatment of diseases for which the FDA had not provided an approved indication, including bladder cancer, breast cancer, brain cancer, cervical cancer, colorectal cancer, leukemia, lymphoma, melanoma, prostate cancer, renal cancer, thyroid cancer, ovarian cancer, and uterine cancer. Celgene similarly marketed Revlimid for the treatment of diseases for which the FDA had not provided an approved indication, including brain cancer, leukemia, lymphoma, myelofibrosis, and prostate cancer. Although federal law prohibits such "off-label" marketing, Celgene incentivized its sales force to promote Thalomid and Revlimid for off-label uses by, for example, paying bonuses tied to the total number of prescriptions written for Thalomid and Revlimid.

376. During the relevant time period, Celgene entered into agreements with physicians to use continuing medical education ("CME") programs as a vehicle to promote off-label uses of Thalomid and Revlimid. In addition, Celgene made payments to numerous physicians to serve as "speakers" and "thought leaders" for the purpose of inducing those physicians (and others) to write prescriptions for Thalomid

and Revlimid. These were effectively agreements between Celgene and the physicians to prescribe Thalomid and Revlimid instead of other drugs for off-label uses.

377. During the relevant period, and as detailed further in Section XII., *infra*, Celgene entered into secret agreements with certain "independent" third-party charities – primarily the Chronic Disease Fund (or "CDF," now called the Good Days Fund) and Patient Access Network Foundation ("PANF") – to use those charities as conduits to underwrite copayments for Thalomid and Revlimid. Through this process, which is barred by federal law, Celgene reduced or eliminated any concerns that physicians or patients would have had about the cost of Thalomid and Revlimid – leaving TPPs solely responsible for paying for those prescriptions. As a proximate result of those agreements, Celgene was able to, and did, increase the quantity sold of Thalomid and Revlimid. These agreements between Celgene and CDF and PANF harmed competition in the markets for Revlimid and Thalomid and other oncology drugs.

VII. CELGENE INTENDED TO AND DID HARM COMPETITION

378. Celgene's scheme was intended to and did in fact block and delay generic thalidomide and lenalidomide entry into the market, disrupted the normal distribution channels, and manipulated the statutory and regulatory mechanisms by which generic competition takes place, and otherwise excluded generic competitors from efficiently marketing and distributing their products.

379. But for Celgene's anticompetitive scheme, generic Thalomid would have been brought to market possibly as early as 2006 (and at the very least, long before generic Thalomid actually entered the market). Celgene illegally prevented

competitors, including Mylan in 2004 and both Lannett and Barr in 2006, from obtaining Thalomid samples for BE testing. When Barr filed its ANDA in September 2006, Celgene filed a sham litigation suit to enforce its invalid and unenforceable patents. The litigation was halted when Celgene and Barr reached a confidential settlement which resulted in a continued absence of generic Thalomid from the market.

380. But for Celgene's anticompetitive conduct, generic Revlimid would have entered the market as early as 2009 or 2010 (and at the very least, long before generic Thalomid actually entered the market). Celgene once again prevented multiple competitors including Mylan, Natco Pharma, Dr. Reddy's, Teva, and Watson from obtaining Revlimid from Celgene for BE testing. Celgene refused to supply samples to Mylan, and Mylan has been unable to complete BE testing or file an ANDA for lenalidomide. Natco filed its lenalidomide ANDA in September 2010 and would have brought generic Revlimid to market shortly thereafter, but for Celgene's sham patent infringement lawsuit and the subsequent settlement wherein Natco agreed not to sell generic lenalidomide until 2022, in limited quantities. Dr. Reddy's filed its lenalidomide ANDA in 2016, after which Celgene once again filed a sham patent litigation which is still pending. Lannett filed its thalidomide ANDA in December 2014, after which Celgene filed a sham patent litigation that resulted in a settlement wherein Lannett's thalidomide could not be sold until August 2019. Zydus, CIPLA, Lotus, and Sun each filed lenalidomide ANDAs and were met with Celgene's serial sham litigation tactic, delaying the entry of their generic Revlimid products into the market.

381. All of Celgene's patents on Revlimid are invalid under 35 U.S.C. §§ 101, 102, 103, 112, and/or doctrines of double-patenting.

382. Celgene's unjustifiable refusal to cooperate with the generic ANDA filers directly prevented generic filers from obtaining FDA approval. But for Celgene's unlawful conduct, the FDA would have given final approval to the pending generic manufacturer's ANDAs and allowed them to enter the market.

383. Celgene cannot justify its scheme by pointing to any offsetting procompetitive or consumer benefit. Generic drugs offer enormous cost savings, which outweigh any non-pretextual, if there even are any, justifications Celgene could possibly offer.

VIII. CELGENE'S ANTICOMPETITIVE CONDUCT CAUSED UHS AND ITS PHARMACY ASSIGNORS TO PAY MORE THAN THEY WOULD HAVE PAID BUT FOR THAT CONDUCT

384. Celgene's scheme suppressed the ability of generic Thalomid and Revlimid substitutes to compete in the market under the governing statutory and regulatory scheme.

385. The absence of generic competition injured UHS and its Pharmacy Assignors because they would have paid much less for Thalomid and Revlimid, or their generic alternatives, by substituting less expensive AB-rated generic drugs for more expensive branded drugs, receiving lower prices on any remaining purchases or payments for branded drugs, and by purchasing generic versions of Thalomid and Revlimid at lower prices sooner.

386. Thalomid and Revlimid were deemed "therapeutic equivalents" for the treatment of MM. Had a generic version of Thalomid been available, users of both Thalomid and Revlimid would have switched some number of prescriptions to the lower-cost generic alternatives.

387. As a direct and proximate result, UHS and its Pharmacy Assignors sustained (and continue to sustain) substantial losses and damages to its business and property in the form of overcharges paid for Thalomid and Revlimid, the exact amount of which will be the subject of proof at trial.

388. The impact of Celgene's conduct on the prices and quantities sold of the drugs at issue is measurable and quantifiable. Commonly used and well-accepted economic models can be used to measure both the existence and the amount of the supra-competitive charges paid by UHS and its Pharmacy Assignors as well as the amount of prescriptions that would have been switched to generic alternatives but for the anticompetitive conduct alleged in this Complaint.

389. Celgene's anticompetitive conduct and/or its effects are ongoing, and, as a result, UHS and its Pharmacy Assignors continue to pay supra-competitive prices for each of the drugs at issue. UHS therefore seeks injunctive relief as well as damages for all injuries proximately caused by the unlawful conduct.

IX. CELGENE'S ANTICOMPETITIVE CONDUCT AFFECTED INTERSTATE COMMERCE FOR THOSE DRUGS

390. At all material times, Thalomid and Revlimid, manufactured and sold by Celgene, were shipped across state lines and sold throughout the United States.

391. Between at least 2010 and the present, in connection with the purchase and sale of Thalomid and Revlimid, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

392. At all material times, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Celgene as charged were within the flow of, and have substantially affected interstate commerce, money, contracts, bills, and other forms of business communications were transmitted in a continuous and uninterrupted flow across state lines.

X. CELGENE MAINTAINED MONOPOLY MARKET POWER OVER THALOMID AND REVLIMID AND THEIR GENERIC FORMS

393. At all relevant times, Celgene has had power over the market for Thalomid and Revlimid in all their forms and dosages, which are still only available in the form of branded Thalomid and branded Revlimid. Celgene has, and continues to have, the power to maintain and increase the price of Thalomid and Revlimid to supracompetitive levels without losing sales, because Celgene has successfully conspired to keep AB-rated generic versions of Thalomid and Revlimid from reaching the U.S. market at all.

394. A small, but significant, non-transitory price increase for Revlimid or Thalomid by Celgene would have been profitable.

395. Celgene needed to control only Thalomid and Revlimid and their AB-rated generic equivalents, and no other products, to maintain the price of Thalomid and Revlimid at supracompetitive prices. Only the market entry of a competing AB-rated generic version of those drugs would render Celgene unable to maintain its market monopoly.

396. If UHS is legally required to prove market power through circumstantial evidence by first defining a relevant product market, the relevant market for Thalomid is all dosages of thalidomide, *i.e.*, Thalomid and its AB-rated generic equivalents, and for Revlimid is all dosages of lenalidomide, *i.e.*, Revlimid and its AB-rated generic equivalents.

397. Thalomid and Revlimid do not exhibit significant, positive cross-elasticity of demand regarding price with any other product, due to the FDA regulatory hurdles incident to securing AB rating and laws allowing pharmacists to substitute only AB-rated generics for prescribed branded drugs.

398. There are no interchangeable drug products available for payors and/or purchasers of Thalomid and Revlimid.

399. Celgene needed to control the output of Thalomid and Revlimid and its AB-rated generic equivalents only, and no other products, to maintain the price of Thalomid and Revlimid profitably at supracompetitive prices. Only the market entry of a competing AB-rated generic version of Revlimid or Thalomid would render Celgene unable to profitably maintain its current prices of those drugs without losing substantial sales.

400. Celgene also sold branded Thalomid and Revlimid well over marginal costs, and substantially more than the competitive price, and enjoyed unusually high profit margins.

401. Celgene has had, and so exercised, the power to exclude and restrict competition for Thalomid and Revlimid.

402. Without the power to exclude and restrict competition for Thalomid and Revlimid, and the ability to sell its own branded version of those drugs at prices well over marginal costs, it would not have been economically rational for Celgene to pay Natco, and potentially other generic manufacturers, unusually exorbitant settlement payments to delay the launch of generic Thalomid and Revlimid.

403. At all relevant times, Celgene has enjoyed the benefits of high barriers to entry with respect to competition to the above-defined market due to patent and other regulatory protections.

404. The relevant geographic market is the United States and its territories, including (but not limited to) Minnesota. At all relevant times, Celgene's market share in the relevant market was, and continues to be, 100%.

XI. ANTITRUST INJURY

405. Celgene's use of the regulatory process as an anticompetitive tool to block and delay generic competition for Thalomid and Revlimid keeps prices high for both direct purchasers like Pharmacy Assignors and end-payors like UHS.

406. UHS and its Pharmacy Assignors paid substantial sums for Thalomid and Revlimid during the relevant times. Because of Celgene's illegal conduct, UHS and its

Pharmacy Assignors have been compelled to pay artificially inflated prices for Thalomid and Revlimid. Those prices have been substantially higher than the prices that would have paid (either for the branded or generic versions of those drugs) but for the illegal conduct alleged. UHS continues to pay artificially high, supracompetitive prices for Thalomid and Revlimid as a direct and proximate result of Celgene's anticompetitive conduct.

407. Consequently, UHS and its Pharmacy Assignors, having paid for Thalomid and Revlimid, have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount, forms, and components of such damages will be determined after discovery and upon proof at trial.

408. Celgene's efforts to restrain competition in the defined relevant markets has and continues to substantially affect interstate and intrastate commerce throughout the United States.

409. Excluding generic competitors prevented price competition for Thalomid and Revlimid.

410. Prices for Thalomid and Revlimid have been and will continue to be inflated as a direct and foreseeable result of Celgene's anticompetitive conduct. The inflated prices that UHS and its Pharmacy Assignors have paid and will continue to pay are traceable to, and are the proximate foreseeable result of, Celgene's overcharges.

XII. CELGENE SEPARATELY EMPLOYED A CHARITY CO-PAY SCHEME BASED ON DECEPTIVE PRACTICES AND FALSE PRETENSES TO FURTHER ARTIFICIALLY INCREASE PRICES AND SALES, HARMING UHS AND OTHER HEALTHCARE PAYORS.

411. Having worked to exclude generics from the market under the conduct described above and secure for itself a monopoly in the markets for Revlimid and Thalomid, Celgene consistently raised the price of Revlimid and Thalomid year-over-year, despite the fact that Celgene knew that many patients already had a difficult time paying for their out-of-pocket share of the drugs.

412. At the end of 2007, for example, a single dose of Revlimid cost $247.28.

413. That year, Celgene began making substantial "donations" to certain purportedly "independent" third-party charities—primarily the Chronic Disease Fund (or "CDF," now called the Good Days Fund) and Patient Access Network Foundation ("PANF").

414. Celgene realized that it could overcome doctor and patient cost concerns, as well as drive up prescription volume, by secretly subsidizing patient co-payment, co-insurance, or deductible (collectively, "co-pay") obligations for its drugs through such charities.

415. On information and belief, since 2007, Celgene has made purported "donations" to CDF and PANF in amounts estimated to be between $50 and $100 million per year.

416. In fact, Celgene deceptively, and under false pretenses, used CDF and PANF as conduits to secretly funnel and disguise payments to both private and

Medicare insurance beneficiaries, including members on UnitedHealthcare Plans. Celgene's payments, as intended, operated to offset beneficiaries' cost-sharing obligations under their health plans, and allowed Celgene to artificially inflate the prices of Revlimid and Thalomid as ultimately paid by third party payors—including UHS—as well as to steer patients away from lower cost alternative oncology drugs.

417. CDF and PANF used money they received from Celgene to pay patients' co-pays for Revlimid and Thalomid, just as Celgene intended, thereby keeping patients and doctors from objecting to Celgene's consistent price increases for the drugs.

418. Celgene thus used the co-pay charities (that Celgene funded) to effectively relieve a remaining market constraint on the prices that it could charge for its drugs, *i.e.*, patient and doctor sensitivity to price.

419. It is well recognized that an insured's co-pay cost-sharing obligations serve as a market-based check on drug pricing and prescription volume. By surreptitiously underwriting these cost-sharing obligations, Celgene created the illusion for physicians and patients that Revlimid and Thalomid were "free" (or close to it) when, in fact, Celgene had merely shifted to third-party payors the entire price burden. Celgene knew it could easily make up the losses it incurred in making the payments to the charities with the profits earned from increasing prices and additional sales.

420. For these reasons, the federal government has long instructed that such conduct violates federal law as unlawful "kickbacks" when conducted in connection with patients insured under Medicare, Medicare Advantage, and Medicare Part D plans. For example, in 2005, the United States Department of Health and Human

Services, Office of the Inspector General ("OIG") issued a "Special Advisory Bulletin on Patient Assistance Programs," warning that pharmaceutical manufacturers' subsidization or influence or affiliation in providing assistance for patients' cost-sharing obligations—whether "directly or indirectly" (including "through" a charity)—is illegal.[93] Among other things, it noted:

- The improper "use of cost-sharing subsidies to shield beneficiaries from the economic effects of drug pricing, thus eliminating a market safeguard against inflated prices."
- "So long as the manufacturer's sales price for the product exceeds its marginal variable costs plus the amount of the cost-sharing assistance, the manufacturer makes a profit. **These profits can be considerable, especially for expensive drugs for chronic conditions.** We are concerned that pharmaceutical manufacturers may seek improperly to maximize these profits by creating sham "independent" charities to operate PAPs; **by colluding with independent charity programs to ensure that the manufacturer's contributions only or primarily benefit patients using its products** . . ." (emphasis added).

421. In 2014, OIG issued a Supplemental Bulletin on pharmaceutical companies' "indirect remuneration to patients" through "contributions to PAP[s]"

[93] 70 Fed. Reg. 70623-03 (Nov. 22, 2005).

operated by independent charities.[94] In that Supplemental Bulletin OIG reiterated that "[i]f a donation is made to a PAP to induce the PAP to…arrange for the purchase of the donor's federally reimbursable items, the [antikickback] statute could be violated.

422. In the 2014 Bulletin, OIG expressed specific concern regarding situations where non-profits "define[d] their disease funds so narrowly that earmarking effectively results in a donor's subsidization of its own products." OIG noted that "[a] charity with narrowly defined disease funds may be subject to scrutiny if the disease funds result in funding exclusively or primarily the products of donors or if other facts and circumstances suggest that the disease fund is operated to induce the purchase of donors' products." As a result, funds are "subject to more scrutiny if [they are] limited to a subset of available products, rather than all products approved by the Food and Drug Administration (FDA) for treatment of the disease state(s) covered by the fund or all products covered by the relevant Federal health care program when prescribed for the treatment of the disease states (including generic or bioequivalent drugs)."

423. In the Supplemental Bulletin, OIG also emphasized that independent charities cannot "give a donor any information that would enable a donor to correlate the amount or frequency of its donations with the number of aid recipients who use its products or services or the volume of those products supported by the PAP."

424. In facilitation of its scheme here, Celgene maintained close contact and worked in coordination with the charities to effectuate its goals. Celgene's payments

[94] 79 Fed. Reg. 31120-31123 (May 30, 2014).

were not made on an ad hoc basis. Instead, they were based on contractual arrangements under which Celgene agreed to pay designated amounts of money to designated disease funds; and addendums were frequently entered to ensure all co-pays would be funded as co-pay projections (or actual payouts on Celgene drugs) changed. CDF routinely provided Celgene both with co-pay forecasts for the following year as well as co-pay utilization. Indeed, the contracts between Celgene and CDF require CDF to regularly produce status reports to Celgene with information on the number of applicants, average amounts of co-pays, total amounts paid out, and the amount of Celgene's donation that remains available for use. Contracts with PANF require PANF's provision of virtually identical information.

425. CDF and PANF conspired with Celgene and third parties including, upon information and belief, the Lash Group, to provide Celgene with the information it needed to be able to ensure it would fully fund and offset potential co-pays as needed for the continued sale of its own products (notwithstanding the exorbitant prices born by payors), and that it successfully aligned its funding accordingly.

426. Indeed, an internal email sent to the Celgene sales team in 2009 confirmed: "[P]lease be aware that your patients should not be experiencing any issues with co-pay assistance from charitable foundations. All foundations are adequately equipped to manage patients in our disease states through the remainder of 2009 and 2010."

427. Celgene knew this because its agents worked to ensure that Celgene's "donations" to the supposed independent charities were earmarked for certain

"buckets" of funding used to assist patients suffering from the core diseases treated by Revlimid and/or Thalomid.

428. With the information it obtained from these purportedly "independent" charities, Celgene and the charities were effectively able to conduct return on investment (ROI) analyses on the amounts of Celgene's "donations," showing Celgene's profits from this scheme.

429. As one analyst report found in the files of CDF stated, "In other words, $100 million in increased donations to copay assistance programs like those run by the CDF can ultimately generate $1 billion in incremental drug sales for CELG[ENE]."

430. Through its "patient support" team, Celgene also brokered relations between individual patients and the charitable foundations, in order to influence and encourage prescriptions for Revlimid and/or Thalomid (notwithstanding the increasingly high prices to be borne by healthcare payors). This included, for example, communicating with the charities to coordinate and conduct conferences with patients (or their family members) and the charities, in order to drive the desired co-pay result. Emails between Celgene and PANF show that Celgene even knew individual patients' PANF identification numbers, as well as detailed information on such patients whose co-pays could be subsidized.

431. Communications exchanged between CDF with PANF employees reveal that both CDF and PANF understood the purpose and effect of Celgene's payments, stating, for example: "If the CDF were to shut down or curtail its operations significantly it would be a big problem for CELG[ENE] because ***the CDF's copay***

assistance program drives a large proportion of CELG[ENE]'s revenues." (emphasis added).

432. Celgene routinely communicated with the charities to assure that its "donations" were sufficient to keep funds flowing towards potential users of Celgene drugs and drive its profits, while third party payors paid artificially high and increasing prices.

433. Celgene thus employed a deceptive scheme using the false pretense of providing charitable "donations" to "independent" non-profits, which were actually kickbacks and subsidies designed to interfere with market forces and maintain and further inflate the prices and increase the use of Revlimid and/or Thalomid as ultimately paid by healthcare payors such as UHS.

434. In 2017 the IRS began to investigate whether CDF was organized and operated exclusively for exempt purposes within the meaning of IRC § 501(c)(3) or whether CDF provided an impermissible benefit to its pharmaceutical manufacturer donors.

435. On October 25, 2019, CDF and PANF entered into settlements with the DOJ in which they agreed to pay a combined $6 million to resolve allegations that the two "charities" *routinely* engaged in the precisely the type conduct that is the subject of this complaint.

436. As stated by the DOJ:

- "CDF and PANF worked with various pharmaceutical companies to design and operate certain funds that funneled money from the companies to

patients taking the specific drugs the companies sold. These schemes enabled the pharmaceutical companies to ensure that Medicare patients did not consider the high costs that the companies charged for their drugs. The schemes also minimized the possibility that the companies' money would go to patients taking competing drugs made by other companies."

- "CDF and PANF functioned not as independent charities, but as pass-throughs for specific pharmaceutical companies to pay kickbacks to Medicare patients taking their drugs . . . . As a result, CDF and PANF enabled their 'donors' (the pharmaceutical companies) to undermine the Medicare program at the expense of American taxpayers."
- "Both the Chronic Disease Fund and the Patient Access Network used their status as charities to shield the illegal activities of pharmaceutical companies seeking to maximize profits."[95]

437. Thus, the DOJ's investigation revealed that—just as alleged herein—CDF and PANF "conspired" with major pharmaceutical companies to enable such companies to use the charities as a "conduit to pay kickbacks" to patients that elect to take the manufacturer's respective drugs.

438. In public SEC Form 10-k (annual report) filings since 2008, Celgene falsely and/or deceptively reported "*donations* to *independent* non-profit patient

[95] *See* https://www.justice.gov/usao-ma/pr/foundations-resolve-allegations-enabling-pharmaceutical-companies-pay-kickbacks-medicare.

assistance organizations in the United States" as among its overall "Selling, General and Administrative expenses." In 2017, for example, Celgene reported an "increase of $70 million in donations to independent non-profit patient assistance organizations in the U.S."; in 2012, a "$72.0 million increase in donations"; in 2011, an "$11.7 million increase in donations"; in 2008, an "increase in donations . . . of $13.3 million"; and in 2007, "[d]onations to non-profit foundations that assist patients with their co-payments also increased" as compared to 2006."[96]

439. By 2019, the price of a single dose of Revlimid cost $719.82—nearly a 200% increase over the cost of the drug before Celgene started paying patient copayments through CDF and PANF. A single year supply of Revlimid can now cost over $200,000.

440. Celgene's unlawful payments further resulted in the submission of false and misleading claims for reimbursement of the costs of Revlimid and Thalomid as submitted to both Medicare and private insurance plans, including the UnitedHealthcare Plans.

441. Upon information and belief, Celgene further benefited from this illegal scheme by claiming tax deductions for its alleged "donations" to CDF and PANF. It did so despite the fact that the payments were in fact not made for a charitable purpose, but were designed to maintain Celgene's increasing prices, revenues and profits on Revlimid and Thalomid.

[96] *See* http://www.annualreports.com/Company/celgene-corporation.

442. The information alleged in this section was not, and could not have been, reasonably known or discovered by UHS until at least late July 2016, when some such facts were first publicly reported. Around the same time (July 28, 2016), Celgene also first disclosed in an SEC Quarterly Report that it had received a subpoena from the U.S. Department of Justice concerning its relationships with charities that cover patients' expenses for the company's high-priced drugs.

443. In addition, Celgene intentionally and fraudulently concealed its scheme, covering up the true nature of its payments and relationship with charities—including by its pattern and practice since as early as at least 2007 of publicly reporting and characterizing its payments as "donations" for the benefit of "independent" charities—including in its public financial statements—while the payments were in fact kickbacks and/or for the purpose of using the foundations as conduits to effectuate its goals of artificially and deceptively inflating the drug prices and increasing the use of the drugs to increase profits at the expense of healthcare payors like UHS. Celgene's concealment prevented UHS from reasonably discovering the facts underlying Celgene's scheme and UHS' injuries.

XIII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Violation of Federal Antitrust Law - Section 2 of the Sherman Act (Damages/Money Relief with Respect to All Pharmacy Assignor Direct Purchases, and Injunctive Relief)

444. UHS incorporates by reference and re-alleges every preceding allegation as if fully set forth herein.

445. At all relevant times, the markets for thalidomide and lenalidomide were "relevant product markets" because Celgene could (and did) profitably impose significant and non-transitory price increases. The relevant geographic market is the United States.

446. At all relevant times, Celgene possessed the power to control prices, restrict output, or exclude competition in the markets for thalidomide and lenalidomide. At all relevant times, Celgene possessed 100% of the market share in the markets for thalidomide and lenalidomide.

447. Celgene knowingly and willfully engaged in a course of conduct designed to prevent generic manufacturers from entering the market, unlawfully maintain and extend its monopoly power, and artificially increase its profits. As set forth in detail above, this course of conduct included, *inter alia*, refusing to sell or otherwise provide samples of Thalomid and Revlimid to generic manufacturers, fraudulently procuring the Distribution Method Patents and the '886 patent, improperly listing these patents in the Orange Book, improperly filing and prosecuting patent infringement actions against generic manufacturers seeking to compete, paying physicians to write prescriptions for Thalomid and Revlimid, and secretly underwriting the cost of copays for insureds. Celgene's conduct was designed to indefinitely delay the introduction of generic formulations of Thalomid and Revlimid into the market and was in violation of Section 2 of the Sherman Act.

448. Celgene intentionally and improperly maintained its monopoly power with respect to Thalomid and Revlimid in violation of Section 2 of the Sherman Act, 15

U.S.C. § 2. Celgene's monopoly power was maintained through exclusionary tactics, and not from growth or development resulting from a superior product, business acumen, or historic accident. Because of this unlawful maintenance of monopoly power, UHS and its Pharmacy Assignors paid artificially inflated prices for Thalomid and Revlimid.

449. UHS and its Pharmacy Assignors have been injured in their business and property by reason of Celgene's antitrust violations. Their injury consists of having paid and continuing to pay higher prices for Thalomid and Revlimid than they would have paid for such products or their generic equivalents in the absence of Celgene's violations. Such overcharges are the type of injury the antitrust laws were designed to prevent and flows from that which makes Celgene's acts unlawful.

450. Even after generic competition begins, UHS and Pharmacy Assignors will continue to pay supracompetitive prices for generic versions of Thalomid and Revlimid until the market achieves equilibrium.

451. The anticompetitive acts by Celgene had, and continues to have, a substantial and foreseeable effect on interstate commerce by artificially raising and fixing prices for the pharmaceutical drugs at issue throughout the United States.

452. UHS, by virtue of its assignments from Pharmacy Assignors, seeks and is entitled to treble damages under Section 4 of the Clayton Act, 15 U.S.C. § 15, for all overcharges proximately caused by the antitrust violation(s) alleged above. Such damages have been suffered in an amount to be proven at trial.

453. UHS, on its own behalf and by virtue of its assignments from Pharmacy Assignors, is further entitled, under Section 16 of the Clayton Act, 15 U.S.C. § 26, to declaratory relief and an injunction against Celgene restraining and preventing the violations alleged in this Complaint, as well as attorneys' fees and costs, and all other forms of relief available under federal law.

SECOND CLAIM FOR RELIEF

Violation of Minnesota Antitrust Law (Damages/Monetary Relief with Respect to Indirect Purchases/Payments, and Injunctive Relief)

454. UHS incorporates by reference and re-alleges every preceding allegation as if fully set forth herein.

455. As set forth above, Celgene possessed monopoly power in the defined relevant market at all times since its NDAs for Thalomid and Revlimid were respectively approved. Celgene knowingly and willfully engaged in a course of exclusionary conduct designed to prevent generic manufacturers from entering the market and unlawfully extended its monopoly power.

456. Celgene intentionally extended its monopoly power in the relevant market through its anticompetitive and illegal scheme. Thus, UHS paid artificially inflated prices for its indirect purchases Thalomid and Revlimid. There is and was no valid, non-pretextual justification for Celgene's anticompetitive actions. It was Celgene's conscious objective to control prices and exclude competition in the relevant market.

457. As a direct and proximate result of Celgene's conduct, as alleged herein, UHS has suffered injury and damages in an amount to be proven at trial.

458. There is a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Celgene will continue to succeed in its goal of maintaining monopoly power in the relevant market.

459. By engaging in the foregoing conduct, Celgene has intentionally and wrongfully maintained, used, and/or attempted to establish, maintain, or use, monopoly power in the relevant market for the purpose of affecting competition or controlling, fixing, or maintaining price in violation of Minnesota Antitrust Law, Minn. Stat. §§ 325D.49, *et seq.*

460. At all relevant times, UHS, a Minnesota corporation headquartered in Minnesota, was contractually responsible for the payments for the pharmaceutical drugs at issue dispensed to UnitedHealthcare Insureds. UHS entered agreements with PBMs, pursuant to which UHS was, and is, responsible for paying PBMs for pharmaceutical drugs, including the drugs at issue prescribed and dispensed to UnitedHealthcare Insureds throughout the United States. UHS entered these contracts, received invoices, and ensured and administered payment pursuant thereto in amounts totaling several billion dollars for the drugs at issue at its headquarters in Hennepin County, Minnesota. Employees involved with making, processing, and managing payments to the PBMs for UnitedHealthcare Insured's claims for the drugs at issue work and reside in Minnesota. Likewise, employees with knowledge of UHS's agreements and payment relationships work and reside in Minnesota.

461. During the relevant period, through either Celgene itself or the regional and national distributors and retailers that it has engaged for the sale of the drugs at

issue, many millions of dollars' worth of the drugs at issue have been, and continue to be, sold and/or paid for in Minnesota each year.

462. The anticompetitive acts by Celgene had, and continue to have, a substantial and foreseeable effect on Minnesota commerce by artificially raising and fixing prices for the drugs at issue, as were paid in, and/or out from, Minnesota, and otherwise injuring corporations and persons located in Minnesota.

463. Celgene's unlawful activities, as described in this Complaint, affected both intrastate commerce in Minnesota and interstate commerce flowing in to or out from Minnesota, and had direct, substantial and reasonably foreseeable effects upon trade and commerce in Minnesota.

464. As a proximate result of Celgene's violation of Minnesota Antitrust Law, UHS has been harmed by being forced to pay artificially inflated, supra-competitive prices for the drugs at issue dispensed to insureds throughout the United States, and UHS has suffered damages in an amount to be proven at trial.

465. UHS has been injured and will continue to be injured in its business and property by paying more for the drugs at issue than in the absence of Celgene's unlawful conduct in violation of Minnesota Antitrust Law.

466. In light of the foregoing, and other facts to be learned and developed through discovery and/or proved at trial, UHS seeks treble damages under Minnesota law for all overcharges incurred and paid by UHS as a result of Celgene's conduct, as well as attorneys' fees and costs, and all other forms of relief available under Minn. Stat. § 325D.49, *et seq.*

THIRD CLAIM FOR RELIEF

Violation of Various State Antitrust and Consumer Protection Laws (Damages/Monetary Relief for All Indirect Purchases/Payments, In the Alternative)

467. This claim for relief is pleaded in the alternative to the Second Claim for Relief, in the event that the Court disagrees that all of UHS's statutory claims for monopolization damages and/or monetary relief for all payments for drugs dispensed to UnitedHealthcare Insureds (to the extent made indirectly) are governed by Minnesota law.

468. UHS asserts that, by engaging in the monopolization conduct alleged above, Celgene has alternatively violated the antitrust and competition statutes of all states and territories that may provide any relief for indirect purchasers/payors, including but not limited to each the following such laws (provided here as exemplars):[97]

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*,

b. Cal. Bus. & Prof. Code §§ 16600, *et seq.*, Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and the California common law,

c. D.C. Code §§ 28-4503, *et seq.*,

d. Fla. Stat. §§ 501.201, *et seq.*,

e. Hawaii Code §§ 480, *et seq.*,

[97] UHS reserves all rights to assert any and all other state laws that may provide any relief to indirect purchasers/payors (whether conferred by antitrust, unfair deceptive trade practices, consumer protection statutes, or the like).

f. 740 Ill. Comp. Stat. 10/3, *et seq.*,

g. Iowa Code §§ 553.5, *et seq*.,

h. Mass. Gen. L. Ch. 93A, *et seq.*,

i. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*,

j. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*,

k. Minn. Stat. §§ 325D.52, *et seq.*,

l. Miss. Code Ann. §§ 75-21-3, *et seq.*,

m. Neb. Code Ann. §§ 59-802, *et seq.*,

n. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*,

o. N.H. Rev. Stat. Ann. §§ 356.1, *et seq*.,

p. N.M. Stat. Ann. §§ 57-1-2, *et seq*.,

q. N.C. Gen. Stat. §§ 75-2.1, *et seq.*,

r. N.D. Cent. Code §§ 51-08.1-03, *et seq*.,

s. Or. Rev. Stat. §§ 646.705, *et seq*.,

t. 10 L.P.R.A. §§ 257, *et seq.*,

u. R.I. Gen. Laws §§ 6-36-1, *et seq*.,

v. S.D. Codified Laws §§ 37-1-3.2, *et seq*.,

w. Utah Code Ann. §§ 76-10-911, *et seq*.,

x. Vt. Stat. Ann. 9, §§ 2453, *et seq*.,

y. W.Va. Code §§ 47-18-4, *et seq.*, and

z. Wis. Stat. §§ 133.03, *et seq*.

469. In addition, Celgene's conduct further constitutes unfair competition or unfair, unlawful, unconscionable, deceptive, and/or fraudulent acts or practices in violation of the consumer protection statutes including, but not limited to each of the following States and territories:

a. Ark. Code §§ 4-88-101, *et seq*.,

b. Ariz. Code §§ 44-1522, *et seq*.,

c. Cal. Bus. & Prof. Code §§ 17200, *et seq*.,

d. Colo. Rev. Stat § 6-1-105, *et seq*.,

e. D.C. Code §§ 28-3901, *et seq*.,

f. Fla. Stat. §§ 501.201, *et seq*.,

g. Idaho Code §§ 48-601, *et seq*.,

h. 815 ILCS §§ 505/1, *et seq*.,

i. Ind. Code §§ 24-5-0.5-1, *et seq*.,

j. Kan. Stat. §§ 50-623, *et seq*.,

k. La. Rev. Stat. Ann. § 51:1401, *et seq*.,

l. 5 Me. Rev. Stat. §§ 207, *et seq*.,

m. Mass. Ann. Laws ch. 93A, *et seq*.,

n. Mich. Stat. §§ 445.901, *et seq*.,

o. Minn. Stat. § 325D.43, *et. seq*., Minn. Stat. § 325F.69, *et seq*., and Minn. Stat. § 8.31, *et seq*.,

p. Miss. Code. Ann. § 75-24-1, *et seq*.,

q. Missouri Stat. §§ 407.010, *et seq*.,

r. Neb. Rev. Stat. §§ 59-1601, *et seq*.,

s. Nev. Rev. Stat. §§ 598.0903, *et seq*.,

t. N.H. Rev. Stat. §§ 358-A:1, *et seq*.,

u. N.M. Stat. §§ 57-12-1, *et seq*.,

v. N.Y. Gen. Bus. Law §§ 349, *et seq*.,

w. N.C. Gen. Stat. §§ 75-1.1, *et seq*.,

x. N.D. Cent. Code § 51-15-01, *et seq*.,

y. Or. Rev. Stat. §§ 646.605, *et seq*.,

z. 73 Pa. Stat. Ann. §§ 201-1, *et seq*.,

aa. S.C. Stat. Ann. § 39-5-10, *et seq*.,

bb. S.D. Code Laws §§ 37-24-1, *et seq*.,

cc. Utah Code §§ 13-11-1, *et seq*.,

dd. 9 Vt. § 2451, *et seq*.,

ee. Va. Code Ann. §§ 59.1-196, *et seq*.,

ff. W.Va. Code §§ 46A-6-101, *et seq*.,

gg. Wis. Stat. § 100.18; Wis. Stat. § 100.20, *et. seq*., and

hh. Wyo. Stat. Ann. § 40-12-101, *et seq*.

470. The unlawful acts by Celgene had, and continue to have, a substantial and foreseeable effect on the commerce of each above State and territory by artificially raising and fixing prices for each of the drugs at issue paid for, and/or dispensed in each State or territory.

471. Celgene's unlawful activities, as described in this Complaint, affected both intrastate commerce and interstate commerce flowing in to or out from each of the above States and territories, and had direct, substantial and reasonably foreseeable effects upon trade and commerce in each respective State or territory.

472. During the relevant period, through either Celgene itself or the regional and national distributors and retailers that it has engaged for the sale of the drugs at issue, many millions of dollars' worth of those drugs have been, and continue to be, sold in each of the above States and territories every year.

473. As a direct and proximate result of Ceglene's violation of each of the foregoing laws, UHS has been harmed by being forced to pay artificially inflated, supra-competitive prices for the drugs dispensed to insureds throughout the United States, and UHS has suffered damages in an amount to be proven at trial.

474. There was and is a gross and unconscionable disparity between the price that UHS paid and continues to pay for the drugs at issue, and the value received, given that more cheaply priced drugs should have been available, and would have been available, absent Celgene's illegal conduct.

475. UHS has been injured and will continue to be injured in its business and property by paying more for the drugs at issue than in the absence of Celgene's unlawful conduct and violation of the foregoing laws.

476. Celgene's conduct in violation of each of the foregoing laws was done knowingly, willfully, and flagrantly.

477. In light of the foregoing, and other facts to be learned and developed through discovery and/or proved at trial, Plaintiff seeks damages, trebled or multiplied to the full extent permitted by each of the foregoing States and territories, for all overcharges incurred and paid by UHS as a result of Celgene's conduct, restitution, as well as attorneys' fees and costs, and all other forms of relief available.

FOURTH CLAIM FOR RELIEF

Violation of Minnesota Consumer Fraud Act (Charity Co-Pay Scheme Damages for All Indirect Purchases/Payments, and Injunctive Relief)

478. UHS incorporates by reference and re-alleges all of the allegations in Sections III and XII, *supra*, as if fully set forth herein.

479. Through its charity co-pay scheme as alleged above, Celgene's conduct violated Minnesota's Consumer Fraud Act, Minn. Stat. § 325F.69, *et seq.*, which broadly prohibits the "act, use, or employment by any person of any fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby." "Merchandise" is defined to include "any objects, wares, goods, commodities, intangibles, real estate, loans, or services." Minn. Stat. Ann. § 325F.68.

480. UHS is a person and/or consumer entitled to protection under the Minnesota Consumer Fraud Act, which extends claims not only to the literal "consumer" but to any potential plaintiffs affected—whether directly or indirectly—by conduct that violates the statute.

481. UHS is further authorized to maintain this action to recover its damages pursuant to Minn. Stat. § 8.31, subd. 3a. (also known the Minnesota Private Attorney General Act).

482. UHS has been financially injured and damaged by Celgene's unlawful conduct in that it proximately caused artificially inflated prices and increased sales volumes for Revlimid and Thalomid, as paid by UHS. Absent Celgene's conduct, UHS would have paid lower prices for Revlimid and/or Thalomid and incurred lower costs in paying prescription drug claims for drugs dispensed to UnitedHealthcare Insureds.

483. Maintenance of this action—brought by UHS to address, deter, and eliminate Celgene's unlawful and harmful conduct undertaken through a pattern and practice over many years, and affecting innumerable pharmaceutical transactions throughout Minnesota and the United States—also benefits the public.

484. Because Celgene's conduct has had the intended effect of raising prices market-wide, other healthcare payors throughout the United States—both private and public (including federal and state Medicare and Medicaid entities)—have been similarly injured by Celgene's unlawful conduct, paying increased pharmaceutical prices and claim costs associated with Celgene's drugs.

485. As alleged above, Celgene's scheme purposefully relieved the market constraint of patient and doctor cost concerns and/or sensitivities throughout the country, in order to increase the overall prices and volumes, and place the entirety of the cost on healthcare payors, who are forced to absorb them.

486. As Celgene intended, patients (including UnitedHealthcare Insureds) relied on Celgene's co-pay scheme in connection with ordering and taking Thalomid and Revlimid as their medical treatment and accepting "co-pay assistance" from purportedly independent charities (when funds were, in fact, secretly sourced and provided by Celgene)—causing inflated prescription drug claims to be submitted to healthcare payors (including UHS) for payment of the costs of the drugs. Doctors similarly relied on the existence of the co-pay subsidies (purportedly from independent charities) in prescribing Revlimid and/or Thalomid for their patients (including UnitedHealthcare Insureds) in that concerns regarding cost to the patient (or "ability to pay") had been eliminated and/or mitigated. Celgene further fraudulently and/or deceptively concealed from the public, including market participants such as UHS, the true nature of its payments and use of charitable foundations.

487. In addition, UnitedHealthcare Plans require members to share in the cost of their prescription drugs, subject to certain out-of-pocket maximums. Celgene surreptitiously offset members' co-pay obligations and intentionally made it appear to UHS that members had paid money – directly or by using assistance from a bona fide charity – when in fact the payments were actually made by Celgene. By covertly subsidizing members' responsibilities for co-pays through the co-pay scheme alleged herein, Celgene intentionally caused UHS to pay for Revlimid and Thalomid prescriptions that it would not have paid for had it known Celgene was conspiring with CDF and PANF to provide the drugs to members for free.

488. Moreover, UHS serves as a Medicare-approved sponsor of Medicare Part D prescription drug benefit plans[98], including plans branded as AARP Medicare Prescription Drug Benefit Plans ("PDPs"). Compliance with federal health care fraud laws, including the Anti-Kickback Statute, is a prerequisite to receiving payment for prescription drugs under Medicare Part D. Celgene's co-pay scheme set forth herein violated the Federal Anti-Kickback Statute, 18 U.S.C. § 1320a-7b(b), which applies to all Federal health care programs, and unlawfully interfered with the cost-sharing structure of UHS's Medicare Part D plans.

489. Celgene was aware that patients, including UnitedHealthcare Insureds, were in contractual insurance relationships that provide for these requirements, because such requirements are ubiquitous in the industry and, in the case of Medicare, are dictated by statutes and regulations.

490. Upon information and belief, Celgene's unlawful scheme is continuing and ongoing, and UHS continues to suffer harm thereby.

491. UHS will continue to be injured in its business and property by Celgene's unlawful conduct if it is not enjoined.

492. In light of the foregoing, and other facts to be learned and developed through discovery and/or proved at trial, UHS seeks (a) all damages caused as a result of Celgene's conduct, plus attorneys' fees, costs, and interest; (b) a declaratory judgment declaring that Celgene's acts and practices violate Minnesota law; (c) an

[98] *See* 42 U.S.C. § 1395w-101(a)(1).

order enjoining Celgene from continuing to engage in such unlawful acts and practices; and (d) any other relief the Court deems just and proper.[99]

FIFTH CLAIM FOR RELIEF

Unjust Enrichment (Damages/Monetary Relief as to All UHS and Pharmacy Assignor Purchases/Payments for All Conduct)

493. UHS incorporates by reference and re-alleges all of the allegations in paragraphs 1 through 443, *supra*, as if fully set forth herein.

494. To the extent required, this claim is pleaded in the alternative to the other claims and/or causes of action in this Complaint.

495. Celgene has knowingly received significant value and benefits in the form of money (profits), and it would be unjust, unlawful, and/or morally wrong for Celgene to retain those benefits, which were conferred unknowingly and/or unwillingly as a result of Celgene's conduct.

496. Celgene has unlawfully benefited from its sales because of the unlawful and inequitable acts alleged in this Complaint. Celgene unlawfully caused UHS and Pharmacy Assignors, who paid for the drugs at issue, to be overcharged and pay prices that were more than they would have been but for the unlawful actions alleged above.

497. Celgene's financial benefits resulting from its unlawful and inequitable acts are traceable to overpayments by UHS and Pharmacy Assignors.

[99] UHS reserves all rights to assert the laws of any other states/jurisdictions in the event the Court disagrees that all of UHS's statutory claims arising from Celgene's charity scheme are governed by Minnesota law.

498. To their economic detriment, UHS and Pharmacy Assignors have conferred upon Celgene an economic benefit, in the nature of profits resulting from unlawful overcharges.

499. Celgene has been enriched by revenue resulting from unlawful overcharges for the drugs at issue while UHS and Pharmacy Assignors have suffered an impoverishment by the overcharges they paid, imposed through Celgene's unlawful conduct. Celgene's enrichment and the impoverishment to UHS and Pharmacy Assignors are connected.

500. There is no justification for Celgene's retention of, and enrichment from, the benefits they received, which caused an impoverishment to UHS and Pharmacy Assignors, having paid artificially inflated and/or supracompetitive prices that inured to Celgene's benefit, and it would be inequitable for Celgene to retain any revenue gained from its unlawful conduct and the resulting overcharges.

501. UHS did not knowingly and/or willingly provide any of the unlawful benefits received and held by Celgene.

502. UHS and Pharmacy Assignors did not interfere with Celgene's affairs in any manner that conferred these benefits upon Celgene.

503. The benefits conferred upon Celgene were not gratuitous, in that they constituted revenue created by unlawful overcharges arising from Celgene's illegal and unfair actions to inflate the prices of the subject drugs.

504. The benefits conferred upon Celgene are measurable, in that the revenues Celgene has earned due to its unlawful overcharges of the drugs at issue are ascertainable by review of sales and/or payment records.

505. As to payments by UHS, it would be futile for UHS to seek a remedy from any party with whom they have privity of contract. Celgene has paid no consideration to any other person for any of the unlawful benefits it received indirectly from UHS with respect to Celgene's sales of the drugs at issue.

506. As to payments by UHS, it would be futile for UHS to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased or paid for the drugs at issue, as the intermediaries are not liable and cannot reasonably be expected to compensate UHS for Celgene's unlawful conduct.

507. The economic benefit of overcharges and monopoly profits derived by Celgene through charging supracompetitive and/or artificially inflated prices for the drugs at issue is a direct and proximate result of Celgene's unlawful practices.

508. The financial benefits derived by Celgene rightfully belong to UHS, because UHS and its Pharmacy Assignors paid artificially inflated and/or supracompetitive prices during the relevant period, inuring to the benefit of Celgene.

509. It would be inequitable under unjust enrichment principles of Minnesota, or alternatively, all States and territories in the United States except Ohio and Indiana, for Celgene to be permitted to retain any of the overcharges derived from Celgene's

unlawful, unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

510. Celgene is aware of and appreciates the benefits bestowed upon it by UHS and its Pharmacy Assignors. Celgene consciously accepted the benefits and continue to do so as of the date of this filing.

511. Celgene should be compelled to disgorge in a common fund for the benefit of UHS all unlawful or inequitable proceeds received from its sales of the drugs at issue.

512. A constructive trust should be imposed upon all unlawful or inequitable sums received by Celgene traceable to the payments made by UHS and Pharmacy Assignors for the drugs at issue.

513. There is no adequate remedy at law.

514. By engaging in the foregoing unlawful or inequitable conduct depriving UHS and Pharmacy Assignors of lower prices for the subject drugs and forcing them to pay higher prices, Celgene has been unjustly enriched in violation of the common law of Minnesota, or alternatively, all States and territories in the United States except Ohio and Indiana.

XIV. DEMAND FOR JUDGMENT

WHEREFORE, UHS demands judgment against Celgene, as follows:

A. Awarding UHS actual, consequential, compensatory, treble, punitive, and/or other damages, in an amount to be proven at trial, including pre- and post- judgment interest at the statutory rates;

B. Awarding UHS equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Celgene's unjust enrichment.

C. Permanently enjoining Celgene from continuing its unlawful conduct;

D. Declaring the acts alleged herein to be unlawful under the state statutes set forth above, and the common law of unjust enrichment of the states and territories set forth above;

E. Awarding UHS its reasonable costs and expenses, including attorneys' fees; and

F. Awarding all other legal or equitable relief as the Court deems just and proper.

XV. JURY DEMAND

Plaintiff demands a jury trial on all claims so triable under Federal Rule of Civil Procedure Rule 38(b).

Dated: March 6, 2020

BOIES SCHILLER FLEXNER LLP
Hamish P.M. Hume*
Kyle Smith*
1401 New York Avenue, NW
Washington, D.C. 20005
Telephone: (202) 895-7580
hhume@bsfllp.com
ksmith@bsfllp.com

Edward H. Takashima*
401 Wilshire Boulevard, Suite 850
Santa Monica, CA 90401

ZELLE LLP
By: */s/ Elizabeth V. Kniffen*
Elizabeth V. Kniffen (MN Bar #0346329)
500 Washington Avenue South,
Suite 4000
Minneapolis, MN 55415
Telephone: (612) 339-2020
ekniffen@zelle.com

Judith A. Zahid*
Eric W. Buetzow*
44 Montgomery Street, Suite 3400

Telephone: (310) 752-2408
etakashima@bsfllp.com

San Francisco, CA 94104
Telephone: (415) 693-0700
jzahid@zelle.com
ebuetzow@zelle.com

James R. Martin*
Jennifer Duncan Hackett*
1775 Pennsylvania Avenue, NW,
Suite 375
Washington, D.C. 20006
Telephone: (202) 899-4100
jmartin@zelle.com
jhackett@zelle.com

* *pro hac vice* applications to be submitted

ATTORNEYS FOR PLAINTIFF UNITED HEALTHCARE SERVICES, INC.